Managing Drug Supply

The selection, procurement, distribution, and use of pharmaceuticals in primary health care

Management Sciences for Health

CPHE

Prof: Mrs: Nirmala Murthy

Managing Drug Supply

The selection, procurement, distribution, and use of pharmaceuticals in primary health care

Management Sciences for Health

Boston, Massachusetts, U.S.A.

To Ibrahim Majid Seraj, N.M. Sekandar, and Abdullah Omar,
physicians and Ministers of Health.
Different men, serving governments with different philosophies,
but with a shared perspective of the potential role
of pharmaceuticals in the public health
and the determination to take action.

Comments from experience with using this manual and suggestions of supplementary reference material (particularly non-English material) are welcomed. They should be directed to:

Drug Logistics Program
Management Sciences for Health
141 Tremont St.
Boston, MA 02111, U.S.A.

Supported by
Research funds of Management Sciences for Health,
Contract AID/DSPE-C-0073
with the U.S. Agency for International Development,
and a Technical Services Agreement
with the World Health Organization.

DR-400
04700 N81

COMMUNITY HEALTH CELL
LIBRARY
AND
DOCUMENTATION
UNIT
BANGALORE.

Contents

	ACKNOWLEDGEMENTS	v
	PREFACE	vii
	HOW TO USE THIS MANUAL	ix
Section I.	OVERVIEW	
I.A.	Prologue	1
I.B.	The Dimensions of Drug Supply	7
I.C.	Planning for Drug Supply	23
Section II.	SELECTION	
II.A.	What to Buy: The Selection of Drugs	49
II.B.	How Much to Buy: Predicting Drug Requirements	79
Section III.	PROCUREMENT	
III.A.	Introduction to the Procurement Cycle	99
III.B.	How to Buy: Procurement Methods and Terms	113
III.C.	Whom to Buy From: Locating and Selecting Suppliers	147
III.D.	How Good are the Drugs: Quality Assurance	179
III.E.	Who Will Pay: Financing Drug Supplies	207
III.F.	Make or Buy: Local Production Opportunities	241
Section IV.	DISTRIBUTION	
IV.A.	Introduction to the Distribution Cycle	273
IV.B.	Inventory Control	289
IV.C.	Importation and Port-Clearing	323
IV.D.	Design and Operation of Storage Facilities	335
IV.E.	Delivery Strategies	377
Section V.	USE	
V.A.	Promoting Rational Drug Prescribing	399
V.B.	Establishing Good Dispensing Practices	427
V.C.	Encouraging Appropriate Use by Patients	445
Section VI.	MANAGING THE SYSTEM	
VI.A.	Organizing Drug Supply	461
VI.B.	Systematic Cost Reduction	491
VI.C.	Security System	513
VI.D.	Designing Training Programs to Improve Pharmaceutical Logistics	529
	GLOSSARY	553
	SELECTED ANNOTATED REFERENCES	567
	ABOUT MSH, THE EDITORS, AND THE CONTRIBUTORS	581
	PROBLEM INDEX	585

EDITOR

Jonathan D. Quick
Management Sciences for Health

MANAGING EDITOR

Margaret L. Hume
Management Sciences for Health

ASSOCIATE EDITOR

Ronald W. O'Connor
Management Sciences for Health

CONTRIBUTORS

James Bates
Management Sciences for Health/Haiti

Henk den Besten
International Dispensary Association/The Netherlands

Peter N. Cross
Management Sciences for Health/Bolivia

Vimal Dias
National Institute of Management/Sri Lanka

A. Frederick Hartman
Management Sciences for Health

William Hewitt
Pharmaceutical Production Consultancy

Aida A. LeRoy
Health Information Designs/Washington, D.C.

M. Lee Morse
Health Information Designs/Washington, D.C.

Peter J. Rousselle
Management Sciences for Health

GRAPHIC DESIGNER AND ILLUSTRATOR

Michael Prokosch

Manuscript preparation was coordinated by Jacqueline Conte
with the typing assistance of Patricia McCarthy and Madeline Osit.
Ann Buxbaum and Daphne Kempner contributed editorial assistance.

Copyright 1981 © , Management Sciences for Health

Acknowledgements

The writing of this manual was truly a collective effort. Past and present Management Sciences for Health staff, consultants, and other associates contributed to the pool of ideas, many lost to and then restored from the anonymity of project documents. Each chapter was initially prepared by one or two authors and then extensively edited. The primary authors were:

James Bates	Chapters IV.D. and IV.E.
Henk den Besten	Chapter IV.E.
Peter N. Cross	Chapter III.E.
Vimal Dias	Chapters III.B., IV.B., IV.C., and VI.B.
A. Frederick Hartman	Chapters I.C., II.B., V.B., V.C., VI.A., and VI.D.
William Hewitt	Chapter III.F.
Aida A. LeRoy	Chapter II.A.
M. Lee Morse	Chapter V.B.
Ronald W. O'Connor	Chapters I.A., I.B., and VI.A.
Jonathan D. Quick	Chapters I.B., III.A., III.B., III.C., III.D., IV.A., IV.B., V.A., VI.A., VI.B., and VI.C.
Peter J. Rousselle	Chapter III.E.

The manual reflects experiences and insights from every corner of the world, from individuals whose interest and commitment to improving pharmaceutical supply management has had major impact on health care in their own countries or in those which they served. While it is impossible to mention each person and country individually, we are appreciative of those whose experiences have taught us; our debt to them is substantial.

Several individuals and organizations contributed directly to the substance and form of the manual, including: S. Ghazenfar, Avicenna Pharmaceutical Institute, Kabul; Enrique Fefer and Eduardo Carrillo of the Pan American Health Organization; Joel Montague of the Aga Khan Foundation; Kevin Denny, Bert Hirschhorn, and Terry O'Connor, former MSH staff members; the late F. Bisharah, former consultant to the World Health Organization; Mark Novitch of the U.S. Food and Drug Administration; Walsh McDermott of the Robert Wood Johnson Foundation; Jack Richman, formerly with UNICEF; Marvin Sandler of the Interstate Drug Exchange; Rolando Madrid Madrid of the Programa Medicamentos Basicos, Lima; Yeap Boon Chye and Liew Kee Hooi, Pharmaceutical Services, Malaysia; V. J. Holna, Pharmaceutical Services, Papua New Guinea; Per Knut Lunde and Magne Halse from Norway; Warren Berggren, Harvard School of Public Health; and Susan Ueber Raymond of the Center for Public Resources.

Collective enterprises such as this require more leadership and management than most individual creations. MSH has been fortunate in having Jonathan Quick and Margaret Hume sharing these respective roles. Dr. Quick has been the *de facto* leader of the effort since his first extended field investigations several years ago. His initial authorship of many sections and editorial hand in others have put an indelible stamp on the manual. Ms. Hume juggled editorial and managerial responsibility for the entire effort over the last year, and the

completed manual is in large part a testimonial to her judgment, skill, and tact in dealing with a very broad range of participants and pressures.

Preparation of the manual was financed with major support from the research funds of Management Sciences for Health and by an agreement with the Office of Health, U.S. Agency for International Development, managed with the assistance of John Alden, Clifford Pease, Don Ferguson, and Terry Lukas. Early seed funding was arranged and assistance with several country visits provided by F.S. Antezana, H. Nakajima, and V. Fattorusso of the Drug Policies and Management Office of the World Health Organization. Early fieldwork by Jonathan Quick was also supported in part by the University of Rochester School of Medicine Honors Committee.

Ronald W. O'Connor, M.D.
September, 1981

Preface

In a 1975 policy paper, the World Bank concluded that the major causes of poor health in developing countries were demographic factors, malnutrition, sanitary conditions, and poor housing. While the primacy of these factors is undeniable and the value of long-range improvements unquestionable, it is equally important to recognize that it is the diseases which they foster and aggravate that are more directly responsible for death and disability. Fortunately, prevention and treatment of these diseases does not have to wait for the betterment of underlying social conditions -- the diseases themselves can, for the most part, be cured or controlled by the appropriate use of pharmaceutical products.*

Pneumonia, much of it responsive to antibiotics, is among the top three killers in numerous developing countries; diarrheal disease, which kills millions of infants and children each year, can be controlled and its mortality significantly reduced with the use of simple glucose-electrolyte sachets; although vaccines exist to prevent measles and poliomyelitis, these diseases continue to kill or cripple hundreds of thousands each year because the vaccines are unavailable or unused; tuberculosis, for which effective treatment has long been available, also remains a dominant cause of death; and so on.

In addition to the direct health impact of pharmaceutical products, their striking effectiveness against common diseases such as malaria, pneumococcal pneumonia, and intestinal parasites is justifiably impressive to rural populations and can serve to establish credibility for new and sometimes suspect community health workers -- credibility which is essential in achieving long-term environmental and nutritional changes in the basic health determinants.

Despite their powerful public health impact, the annual per capita expenditure for pharmaceuticals remains below one U.S. dollar in many developing countries; the World Health Organization estimates that 60 to 80 percent of the people in the developing world are without access to even the most essential drugs. Nonetheless, a government's limited allocations for drug procurement may account for up to 40 percent of its overall health care budget, making the efficient management of drug expenditures a vital consideration for health officials.

In many countries, high costs and frequent shortages remain chronic problems for drug supply. The reasons for this are many. The role of some commercial pharmaceutical companies in encouraging irrational and excessively costly drug use has been well-documented. At the other end of the spectrum, local health beliefs frequently push physicians and auxiliary medical workers into prescribing practices which deviate sharply from standard medical training and which waste limited drug resources. The limitation of funds for purchasing and distributing drugs nearly always results in apparent shortages in a world of seemingly

---

* In this manual "pharmaceutical products" and "drugs" will be used interchangeably to refer to any drug product used in prevention or treatment, including vaccines, oral rehydration sachets, tablets, capsules, injectables, and galenicals.

insatiable demand. And inefficient storage, transport, and distribution lead to duplication, waste, theft, and spoilage, further depleting an already limited supply.

It is the conviction of the authors and supporters of this manual that substantially greater use could be made of available resources through improved management of the pharmaceutical supply process. Sound supply management practices which are successfully applied in commercial enterprises are seldom applied to public management problems; ironically, these analytic techniques to improve the use of scarce resources have yet to see much application in the settings of greatest scarcity.

At the same time, many innovations and successful experiences of individual developing countries have not been widely shared with other countries. Existing public drug supply programs are striking in the similarity of the basic challenges and pitfalls from program to program and continent to continent, and in the creative diversity of the responses to these challenges. This manual combines the basic concepts of pharmaceutical logistics developed by Management Sciences for Health during a decade of work in this field with the experiences and observations from a host of individual developing countries. In this respect the manual is an "idea book" rather than a text or "how-to" book. Its primary objectives are to assist health decision-makers to:

(1) Identify and clarify the major functions and components of an effective drug supply system;

(2) Assess existing supply services in terms of resources, strengths, and weaknesses;

(3) Design and implement improvements in drug supply systems, combining solid management principles with an understanding of the conditions unique to each situation.

The writers by no means presume to deal with all of the complex and deeply entrenched problems involved in providing basic pharmaceuticals to the public. Many topics of importance are beyond the scope of this manual and have purposely not been included. Among these are the operation of multinational pharmaceutical corporations, the influences of patents on drug prices and availability, the control of prescription drug sales by commercial pharmacies, price control of retail drug sales, and drug development for tropical diseases and other diseases prevalent in developing countries.

We have focused on topics of direct relevance to the supply of pharmaceuticals for primary health care, to provide practical information for governments, international assistance agencies, bilateral aid programs, and charitable organizations. But this manual is a starting place, not a source of instant solutions. Successful implementation of the ideas presented requires a commitment to training the health team involved in the selection, procurement, distribution, and use of drugs; it requires coordination of drug-related activities with other health and human services; and it requires skilled managerial direction and supervision.

Opportunities for increasing the effectivess of health care delivery through improved drug supply management are immense. It is our hope that this manual will help health decision-makers to grasp these opportunities and to make substantive, lasting improvements.

How to Use This Manual

At first glance this volume may seem formidable. Don't panic! It is not intended to be read from cover to cover like a text or programmed learning book. Nor is it meant to be an encyclopedia or reference book for technical details. Instead, it has been written to provide explanations of fundamental supply concepts, definitions of basic terms, and practical ideas for designing and implementing effective changes in drug supply. The length of the manual reflects more the breadth of topics which relate to pharmaceutical supply than the complexity of any of the topics.

To make the material in the manual more accessible to those looking for guidance in specific areas, the following features have been included:

Problem Index -- At the very back of the manual is an index which is arranged by common drug supply problems. Possible solutions to these problems are given along with references to the appropriate chapters and sections of the manual. For readers with specific questions or supply problems, the Problem Index would be the best starting place.

Overview Chapters -- There are several chapters which serve as introductions to specific aspects of pharmaceutical supply. Chapter I.B. provides an overview of the entire supply process, its pitfalls, and the potential for improvement. Chapter I.C. discusses the planning process. The procurement process is reviewed in Chapter III.A. and the design and operation of a distribution network is discussed in Chapter IV.A. Finally, the important elements of supply management are summarized in Chapter VI.A.

Assessment Guides -- Many of the chapters begin with assessment guides, loosely structured series of questions intended to help the reader to understand his own supply system (if one already exists) and to gain more from reading the chapter. These Assessment Guides can and should be freely copied from the manual to stimulate policy discussions, for training workshops, for formal evaluations of supply activities, and for any other supply-related discussions.

Country Studies -- Many people learn best by example. Throughout the manual we have included separate, one-page Country Studies to illustrate points in the text and to provide examples of different approaches to specific aspects of drug supply. Even though conditions in some countries may have changed since the stories were written, the experiences of individual countries provide valid examples of the ways in which the supply process can operate and, in some cases, how it ought not operate.

Chapter Summaries -- At the end of each chapter is a one page "telegraphic" summary of chapter contents. These summaries may be the best source for those interested in a rapid, but complete overview of all aspects of drug supply.

Chapter Appendices -- To help governments and technical advisors locate specific sources of information and additional specialized assistance, several detailed appendices have been included following the appropriate chapters. Management Sciences for Health welcomes any suggestions for additions to the lists or comments regarding specific listings. The major appendices cover information sources for drug selection (II.A.1.), pharmaceutical suppliers (III.C.3.), quality control laboratories (III.D.2.), national control agencies for certifying drug quality (III.D.4.), technical assistance for local productio (III.F.1.), and training programs for pharmaceutical logistics (VI.E.1.).

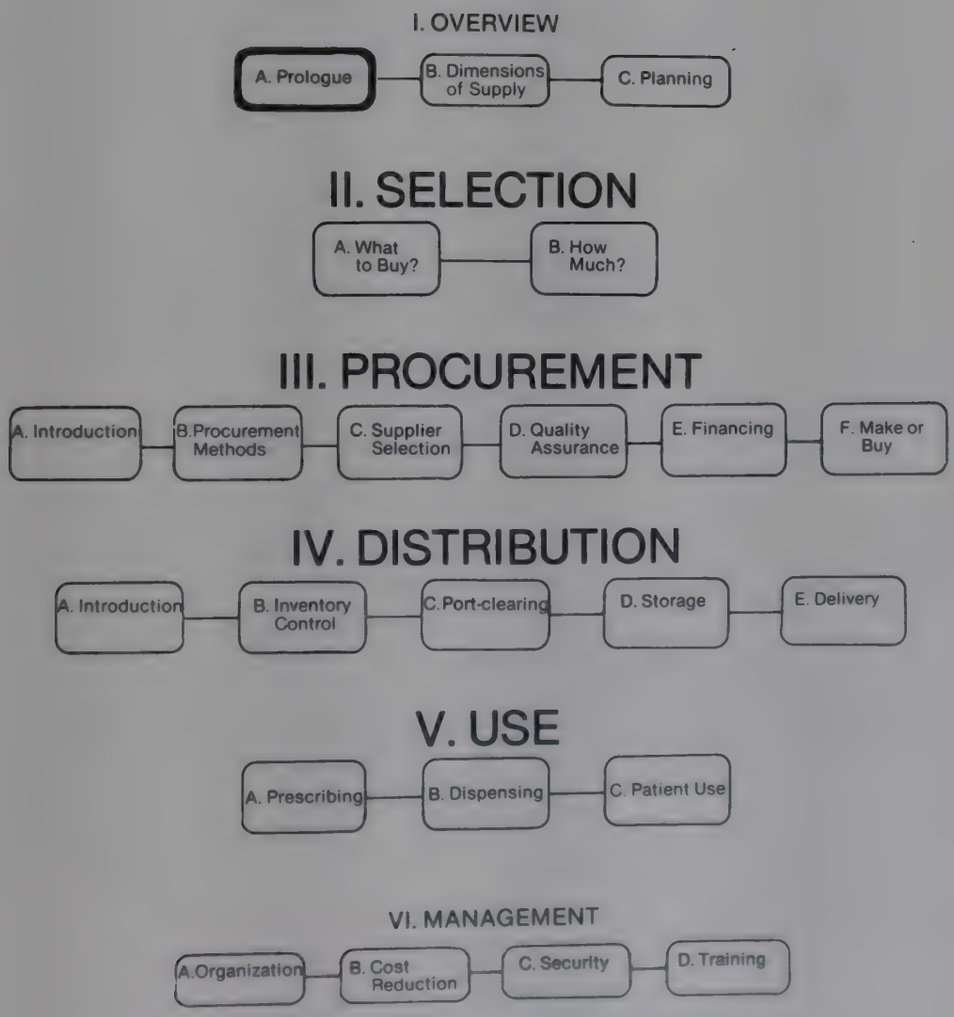
Sample Forms -- Several chapters and some appendices include sample forms for various aspects of selection, procurement, distribution, and drug use. These samples are taken from forms currently in use in different parts of the world and may be copied directly from the manual or used with necessary local modifications. A complete packet of sample forms is available on request from Management Sciences for Health.

References -- Each chapter contains a reference list for more detailed discussion of topics covered in the chapter. Unfortunately, many of these references may be inaccessible to most readers. However, the list of annotated references which appears at the back of the manual has been edited to serve as a "buyer's guide" for those interested in acquiring additional publications in specialized areas of drug supply. Wherever possible, recent prices and publishers' addresses have been included in this list.

Glossary -- The back of the manual also contains a glossary of terms used in the manual. Definitions may vary, depending on local usage, but the ones given in the glossary reflect the usage of terms in this manual.

Chapter I.A.

Prologue



Prologue

The Village

Miguel was worried this time. His two year old son, Juanito, had never been this sick before: he had a cough that wouldn't quit, he felt hot and had a dull, faraway look so different from his usual happy laugh. For a week, his wife, Maria, had tried everything in the house she could think of, yet nothing worked. Her neighbors cautioned against "hot" foods, but Juanito wasn't hungry anyway and hardly ate or drank.

A serious problem, not responding to home remedies

The Village Health Worker

Maria took the boy across the valley to see Ramon who kept a small shop in his farmhouse. Ramon had been selected the year before by the village for training at the health center. From his training, he knew that prolonged fever and cough could be pneumonia. His stock of medicines no longer included packets of penicillin tablets: there had been a lot of chest colds around and now only one packet was left. He broke it open and took out three tablets, embarrassed that he couldn't give the packet and explaining that at last month's resupply meeting no stock was available. Ramon was angry too, behind his words of instruction, thinking of what he'd say to the Health Center Supervisor the next time. Why bother to go to the meetings at all if there were no drugs? He was ashamed to be trying to satisfy the village's needs with advice alone -- it wouldn't do, that's all.

A good diagnosis, but inadequate treatment due to drug supply shortage

Disappointment and skepticism from the patient

A loss of credibility for the health worker

In the Town

Miguel had walked the burro half the night to get to the market early. He sold his load of carrots quickly and took the money to the pharmacy, where he described Juanito's fever and cough. A young boy was tending the shop for his uncle, who was away buying drugs in the city. He remembered people coming in for fever and his uncle giving them pills from a bottle

Untrained dispenser, inaccurate prescribing

labeled chloroquine: he could easily reach it. Miguel was glad to buy the pills and hurried off.

Inappropriate dosage schedule

At home Miguel found Juanito no better. Maria had given him the three penicillin tablets at noon yesterday when she got home, which he had swallowed with difficulty. He smiled weakly as his father attempted to give him a chloroquine tablet, but screamed and spit it out with its bitter taste, his cough and tearless cry sending Miguel and Maria into deeper despair.

The Health Center

Maldistribution of limited supplies

Declining participation in village health program

At the Health Center, one and a half day's walk from the village, Peter, the Supervisor, was not eager to face the Village Health Workers again without enough supplies. It was even worse knowing that the next region had surplus stocks accumulating from two years of deliveries, though village workers had only recently begun work. His own credibility was at stake; their enthusiasm for continuing education was dissolving into discontent and declining attendance, fragmenting the program which had been so enthusiastically received by the villages the year before. He knew he would have to get the Regional Health Office to respond soon, or all momentum would be lost in yet another example of government failure.

The Regional Office

Inadequate salaries contributing to illegal activities

Competing demands for inadequate supplies

Incomplete record-keeping hinders planning

Jose was perplexed. As Regional Health Officer, the hospital was his constant concern (as the central health facility on which two million people depended), yet he had the rural health centers, too. Now both were complaining about drugs. He knew, as did everyone else, that drugs, theoretically free, were sold by some staff members to supplement salaries and income from unofficial private practice. There was never enough to go around, and he could no longer reallocate health center supplies to the hospital -- too much demand in the rural areas now. On top of that he was beginning to wonder about his administrator, whose latest story of shipments lost or arriving undercounted only complicated the problem. If he only knew what was used last year in each center, he'd be able to juggle demands a bit better, at least until the decision on his own transfer was made, and he was out of the mess.

Poor packaging

At the hospital, the pharmacist reached high on the shelf for the last tin of penicillin tablets that was left. The top clattered to the floor as she looked first at the label, not quite outdated, and breathed a sigh of relief -- until she looked inside at the

crystalized mass of tablets, decomposed after the top had been loosened in transit. She had nothing to give the man with the prescription and the woman with the swaddled child gasping in her arms. They turned away, wondering what to do next.

Carlos, the hospital administrator, took pride in his efforts to juggle the region's inadequate health resources. His years of service balanced a lack of training and made him a respected official. He could not, however, figure out how to handle the drug mess, which got worse every year as demand outstripped supply and more health facilities were opened. A few facilities had overstocks while others were always out. It all seemed so unpredictable. Rumors of corruption bothered him most of all, a man whose pride in his work at a difficult job had always been so important. Now, with health workers beginning to provide some simple health services in almost every village, the resupply and financial problems were overwhelming. Carlos understood how tempting valuable drugs were to many staff trying to get by on the small government salary -- but for people to insinuate that he was involved was the most unpleasant thing he had to live with. Now, if only he could get the requisitions and the records together, he could be able to justify his position to Central Medical Stores and get them to release the emergency request he had placed two weeks earlier.

Untrained administrative staff

Supply of new health workers rapidly outgrowing the supply of drugs

Inadequate management information for stock control and financial planning

Central Medical Stores

As Juanito's parents managed to get the seemingly lifeless child admitted to the pediatric ward of the hospital, Enrique, the Chief of Central Medical Stores, searched into the evening to find the intravenous penicillin required. His anger at the disorganization of the warehouse exhausted him more than the search.

Warehouse disorganized

Enrique was responsible, he knew, but how could he do it all? The stock reports were disorganized and he never had found time to train the clerks. The late arrival of shipments cleared from customs after sitting on the wharf in the rain had compounded the mess, with crates and cardboard a soggy stew all over the floor. And the stock count suggested more losses on the docks or in transit than just to rats and rain.

Untrained staff

Mis-estimated lead times, pilferage, spoilage, port-clearing problems

At last he found the penicillin and sent it off with the pharmacy aide and frightened farmer. He was too tired to think about the endless emergency requests from the regions which always seemed to pile in, especially when vehicles were down, awaiting parts. Even

Transportation confusion and vehicle breakdown

Expensive emergency purchase; supplier default

worse, tomorrow he would have to try to get approval for an airfreight purchase of penicillin tablets since the lowest bidder had defaulted on the shipment. It would cost a fortune on such short notice....

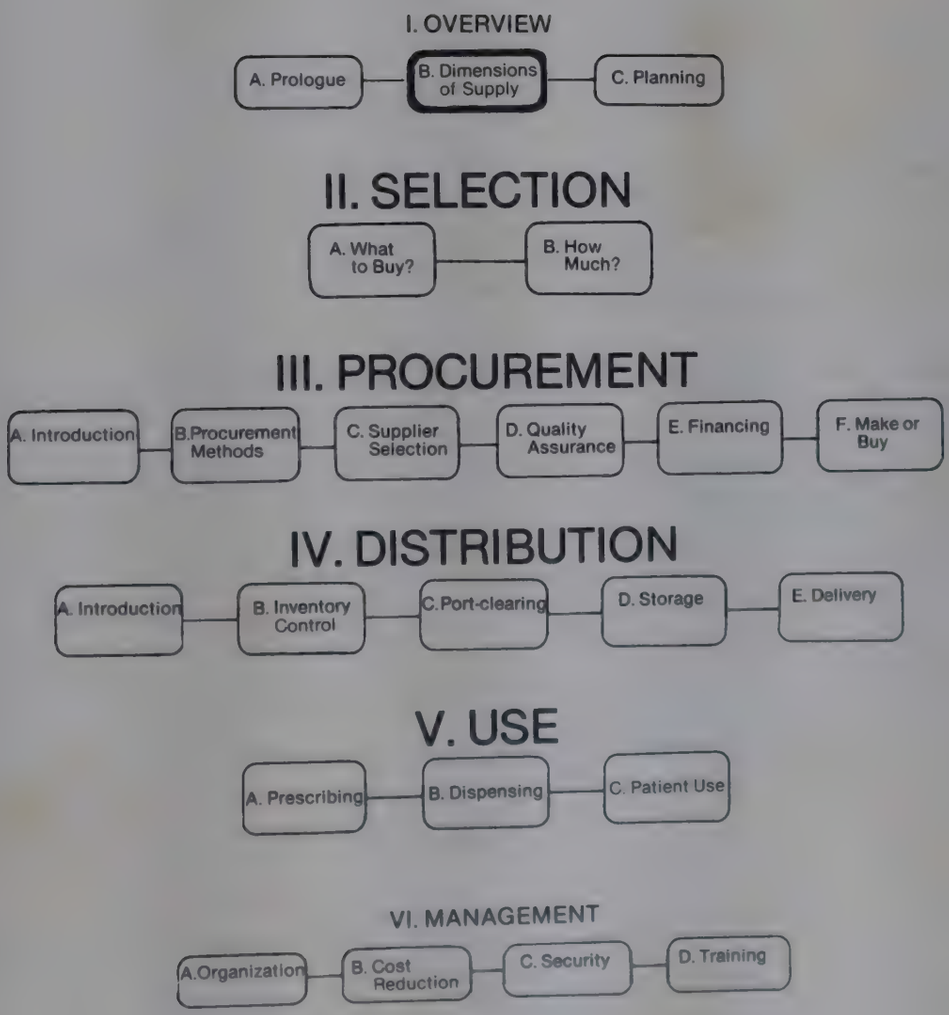
* * *

Continuing hardship and uncertainty

On a truck heading back toward the village, Miguel was a mixture of emotions. He was relieved that the doctors had taken Juanito into the big hospital and that Maria could stay at his side. But he was frightened by the plastic tubes he had had to buy at the pharmacy, which were now connected to Juanito's arm. And he was fearful for the future. Life would be very hard again, now that he would have to sell some of his animals to pay for medicines. But he thanked God that Juanito still had a chance.

Chapter I.B.

The Dimensions of Drug Supply



		Page
1.	WHY WORRY ABOUT DRUG SUPPLY?	9
	Drugs Improve Health Drugs Promote Trust and Involvement in Health Services Drugs are Costly Substantive Supply Improvements are Feasible	
2.	THE SUPPLY PROCESS AND ITS PITFALLS	11
	Selection Procurement Distribution Use	
3.	WHAT CAN BE ACCOMPLISHED?	14
4.	PLANNING AND IMPLEMENTING CHANGE: MANAGING THE BUILDING BLOCKS	18
	Administration Information System Personnel Facilities Equipment Finances	
5.	FUNDING: THE UNIVERSAL CONSTRAINT	20
	SUMMARY	21
	REFERENCES	22

The Dimensions of Drug Supply

1. WHY WORRY ABOUT DRUG SUPPLY?

The availability of trained staff and facilities which are accessible to the population are necessary components of primary health programs, but they alone are not sufficient to provide effective health care. Pharmaceuticals, including vaccines, pills and capsules, oral rehydration sachets, intravenous solutions, and other drug products must also be available. Their importance for primary health programs must be recognized in light of the following four observations:

- Drugs improve health.
- Drugs promote trust and involvement in health services.
- Drugs are costly.
- Substantive supply improvements are feasible.

These observations have provided the primary motivation for the preparation of this manual. The richness and diversity of opportunities for practical, effective improvements in pharmaceutical supply are the focus for most of the following chapters.

Drugs Improve Health

Leading causes of discomfort, disability, and death in the developing world are often preventable or treatable with pharmaceutical products. The underlying contribution of malnutrition, poor sanitation, inadequate housing, and economic deprivation to poor health cannot be ignored. But at the same time, few would deny the importance of essential and potentially life-saving medicines. Measles immunization eliminates a major child killer, penicillin can prevent many pneumonia deaths, contraceptives foster effective family planning, and oral rehydration salts in the home allow mothers to treat diarrheal disease. The long-term impact of vaccines and the immediate effect of other drugs provide compelling arguments for assuring a steady supply of basic pharmaceuticals for any population.

Drugs Promote Trust and Involvement in Health Services

The availability and effectiveness of drugs is a key factor in generating and maintaining public interest and participation in health-related activities. Initially, the credibility of health workers depends on their ability to bring an end to weeks of fever with a treatment of chloroquine, to save a dying elder with a course of penicillin, or to quiet a crying child with aspirin. Adequate and timely supply of contraceptives is essential for family-planning programs to have a noticeable impact on fertility and, thereby, to gain public acceptance.

A rural health survey in one Asian country revealed that the villagers valued drugs more than they did the health workers or clinic. In a Latin American country embarking on a comprehensive rural health program, community health workers turned to private pharmacies to replenish their drug stocks when program supplies failed them. This was necessary, the health workers said, because without drugs they could not maintain public interest in preventive services and health education. Thus, improvements in the basic health determinants, such as nutrition and sanitation, depend in part on the trust and involvement which health workers can engender through their effective use of pharmaceuticals. In many settings irregular drug supply may be a greater constraint on program effectiveness than the lack of health workers themselves.

Drugs are Costly

Health officials are likely to find no other issue of comparable economic impact upon which they can take direct action. Even in Europe and North America, drugs constitute 10%-20% of expenditures for health care. In developing countries, the economic impact of drug costs for government programs is immense, often representing as much as 40% of health care budgets. In some of the least advantaged countries, import costs of wholesale drugs have been found to equal the entire national health operating budgets for salaries, services, and other supplies, and at the household level, expenditures for medicine make up a sizeable chunk of family budgets.

In a remote rural area of Afghanistan, for example, 7% of total household income, both cash and non-cash, is spent on health needs. One-third of this figure goes for drug purchases in the commercial sector -- in villages that do not even have full-time shops. For the target population of a government rural health center in Afghanistan, the estimated annual value of drugs purchased on the open market is 47 times the annual value of drugs dispensed through the health center. Therefore, any steps taken by a health manager to reduce the cost and improve the effective delivery of drugs may have significant impact on the economic and health status of individuals and their families.

Substantive Supply Improvements are Feasible

The most encouraging observation about pharmaceutical supply is that useful improvements can be, and are being, made in a wide variety of circumstances. More systematic drug selection requires little in terms of additional funding, staffing, or equipment; yet it can save substantial amounts of money in a short period of time. Improved procurement practices require minimal material resources to implement, but their effects on reducing costs and improving the regularity of supply are quickly felt. Dependable distribution of drugs may require additional vehicles or fuel, but with improved management these investments can yield an impressive return. Innovations like course-of-therapy prepackaging involve additional start-up and operating costs, but their impact on improved patient use of medicines almost always justifies the investment.

The opportunities for improvement in drug supply are many and diverse, but they do require a complete knowledge of supply systems, a carefully devised plan, and qualified staff members or advisers. Nearly every country

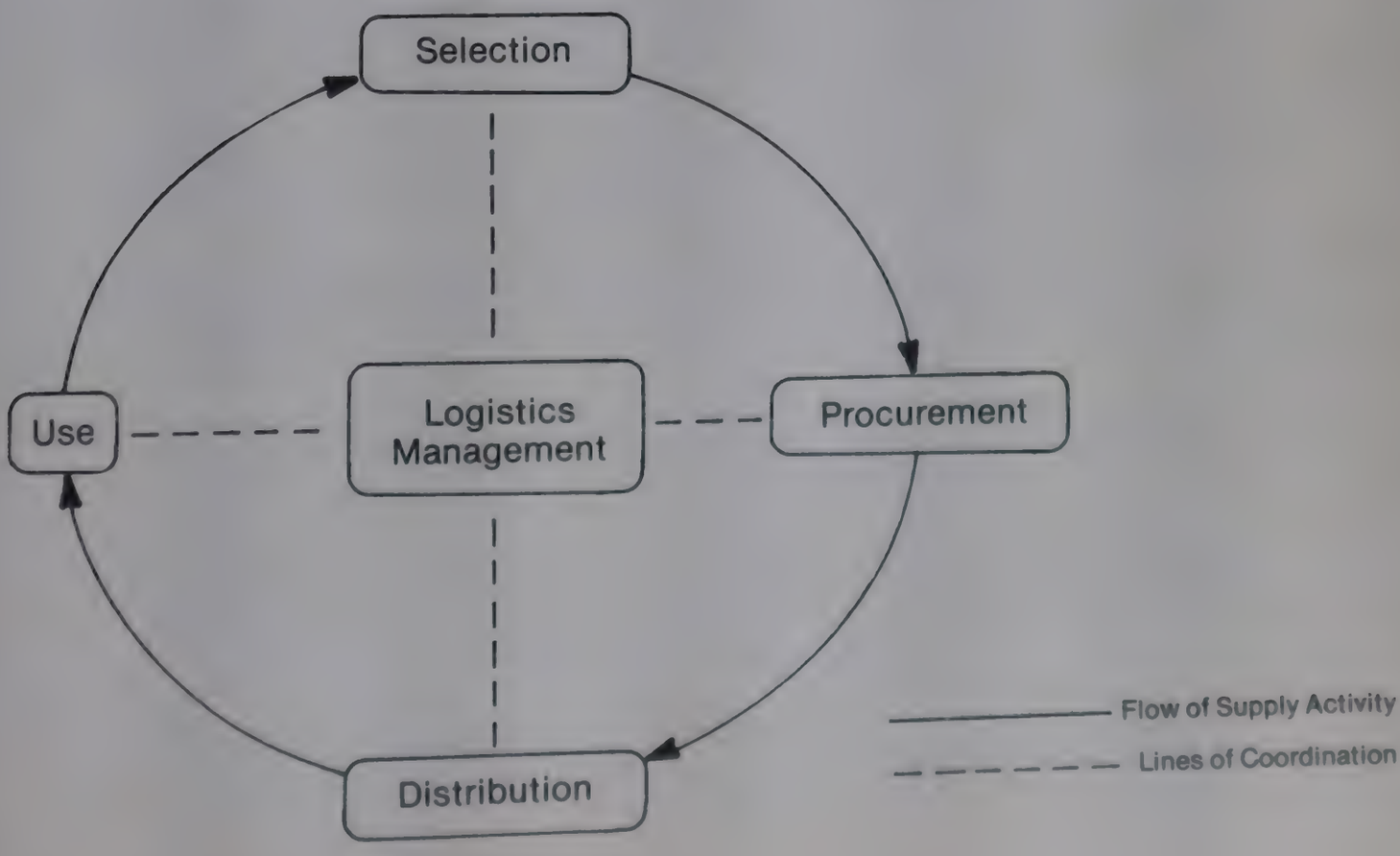
has some means of delivering drugs to the public sector. It is seldom possible or even necessary to completely rebuild the supply system, but is is possible to make improvements in specific problem areas that can visibly improve performance and allow health managers to make a lasting impact. Planning for improvements depends first upon an understanding of the supply process and the common pitfalls in this process.

2. THE SUPPLY PROCESS AND ITS PITFALLS

Logistics is the science of procuring, maintaining, and transporting supplies. It involves delivering large amounts of supplies on schedule to many people located in numerous different places. In drug supply, it includes all aspects of the process required to bring a drug from the supplier to the dispenser and, ultimately, to the individual patient. Logistics systems are truly "systems" in that they require the coordinated efforts of many individual units inside and outside the government. When the separate tasks are performed not as part of a system but independently and disjointedly, costs rise, shortages become commonplace, and patients suffer.

The primary functions in the logistics cycle of any drug supply system fall into four categories (Figure I.B.1.):

Figure I.B.1.
The Logistics Cycle



(1) Drug Selection includes issues such as what products should be available and in what quantities.

(2) Procurement includes purchasing methods, finance, terms of payment, sources of supply, quality assurance, and decisions to make or buy a product.

(3) Distribution includes import management, inventory control, storage, waste management, and transport.

(4) Use includes prescribing and dispensing practices, packaging and labeling, training auxiliary personnel, and educating consumers.

Just as the basic functions of a logistics system are similar from country to country, the pitfalls encountered in supplying drugs are surprisingly similar from place to place.

(1) Selection is often inefficient, especially where pharmaceutical knowledge is lacking, information on current therapeutics is unavailable, or the process for selecting drugs is disjointed or haphazard. The results can be:

- purchase of too many products -- an unnecessarily large variety of items may duplicate each other, consume limited inventory capital, and complicate distribution;
- purchase of unnecessarily expensive products -- there are frequently cheaper, equally effective alternatives available;
- purchase of inappropriate products -- limited funds are expended on new drugs whose clinical efficacy has not been established, on unproven combination products, and on symptom-relief preparations when there are insufficient quantities of more essential drugs such as antibiotics and vaccines; and
- purchase of inappropriate quantities -- requirements may be overestimated for some items and underestimated for others.

(2) Procurement refers to obtaining pharmaceuticals, not only through purchase, but also through donations and government production. Problems are frequent with regard to:

- supplier selection -- unreliable suppliers withdraw or change their offers during the tender process, deliver substandard products or goods near their expiration dates, or fail to replace bad batches;
- contract terms -- supplier contracts do not provide adequate product specifications, set labeling and packaging requirements, establish firm price and currency exchange conditions, or provide a mechanism for holding suppliers accountable for their errors;
- quality assurance -- inadequate attention is paid to drug quality prior to purchase and there is a lack of careful monitoring of port, warehouse, in-country transport, and peripheral storage conditions;

- make or buy options -- production possibilities are pursued in areas which are too technical, too expensive, or both, while feasible opportunities for limited local production go unrecognized; and

- financing -- procurement is limited by lack of funds, while the public, even in remote areas, buy drugs at high commercial prices.

(3) Distribution is a complex and highly varied function. In some programs commercial distribution networks are relied on for most deliveries, while in other programs the government assumes the entire responsibility for moving drugs from a central national warehouse all the way to the farthest health post and community health worker. Analysis of distribution networks often reveals difficulties with:

- information mismanagement -- too much information is recorded, too little information is used, or the information obtained from consumption records, vital statistics, accounting records, and other information sources is misused;

- port-clearing -- failure to obtain proper import documents or inexperience with the port-clearing process results in demurrage charges, increased losses from spoilage and theft, and unnecessary delays;

- storage -- spoilage is hastened by overcrowded, disorganized warehouses and customs sheds, inadequate moisture, temperature, or pest controls, and regional distribution facilities even more poorly maintained; limited space is used suboptimally; inadequate security leads to further losses from theft;

- transportation -- disorganized public transport scheduling, poor maintenance, and failure to consider private sector systems slow delivery and increase costs; and

- stock mismanagement -- managers are frequently unaware of what supplies they have on hand or where they are; supplies needed in one region may gather dust in another, because their presence is unknown or because mechanisms for transferring stocks do not exist.

(4) Use of pharmaceuticals is influenced by factors both inside and outside the public health programs. The ability of the logistics system to meet public health needs is highly related to usage patterns. Common problems with the use of drugs include:

- poor packaging and labeling -- containers may be unsuitable for the environment, labels unreadable by the consumer, or packaging quantities inappropriate for dispensing or patient use;

- careless dispensing practices -- dispensing is carried out under unsanitary conditions with dirty utensils; creams and liquids are dispensed into unwashed bottles, and pills are simply wrapped in paper; patients often receive only oral instructions;

- irrational prescribing -- lack of mechanisms to promote uniform prescribing habits results in rampant over- or under-use of drugs; use

of ineffective drugs or unindicated multiple prescriptions requires the supply system to procure, store, and deliver unnecessary items; and

- patient use -- there is noncompliance with treatment due to inadequate instruction, the quantity dispensed, or unrealistic dosage schedules.

These are only a sampling of the many problems that exist to hinder the effective delivery of pharmaceuticals through primary health programs. For all of the problems discussed here, there are potential solutions. It is the aim of this manual to help managers seek out the solutions and implement them in settings where they can make a difference.

3. WHAT CAN BE ACCOMPLISHED?

Many developing countries are demonstrating that much can be accomplished to improve pharmaceutical supply. Such improvements can be made largely with existing resources, without waiting for technological breakthroughs, and in the face of the inevitable constraints of history, custom, political relations, and private interests.

Figure I.B.2. illustrates the typical flow of drugs in a public supply system. In some systems, drugs will be procured at the regional, district, or even community level (broken lines in Figure I.B.2.). Interaction between a public health program and commercial suppliers may occur at the national level, where only raw ingredients are purchased and the drugs are produced and distributed entirely by public institutions, or the interaction may begin at any point down to the community level, where drugs are purchased directly from commercial pharmacies or shops. The level at which supplies are procured is dependent to a large extent upon whether drug supply is a centralized or decentralized function. Alternative organizational structures are discussed in Chapter VI.A.

When considering the public-private interface, it is important to recognize the potential value of cooperative ventures. Commercial suppliers can sometimes assist with quality assurance programs, with specific training programs, with locating specific articles and other scientific information for use in drug selection, with arranging economical distribution of drugs to health facilities, and with other aspects of drug supply. Successful cooperative efforts benefit public health programs by increasing the quality and efficiency of supply services. Increased efficiency benefits the commercial suppliers by making more funds available for drug procurement. Finally, the public benefits because more supplies are available at lower unit prices.

To make substantive, lasting improvements in drug supply, it is important to view the supply system as a part of the total health care system. Drug supply also occurs within the broader context of other government activities -- financial management, defense, economic development, etc. -- with which drug supply activities may be coordinated, competitive, or entirely unrelated. Finally, all of these activities occur within the larger national, political, economic, and social framework (Figure I.B.3.).

Figure I.B.2.

Typical Public Drug Supply System

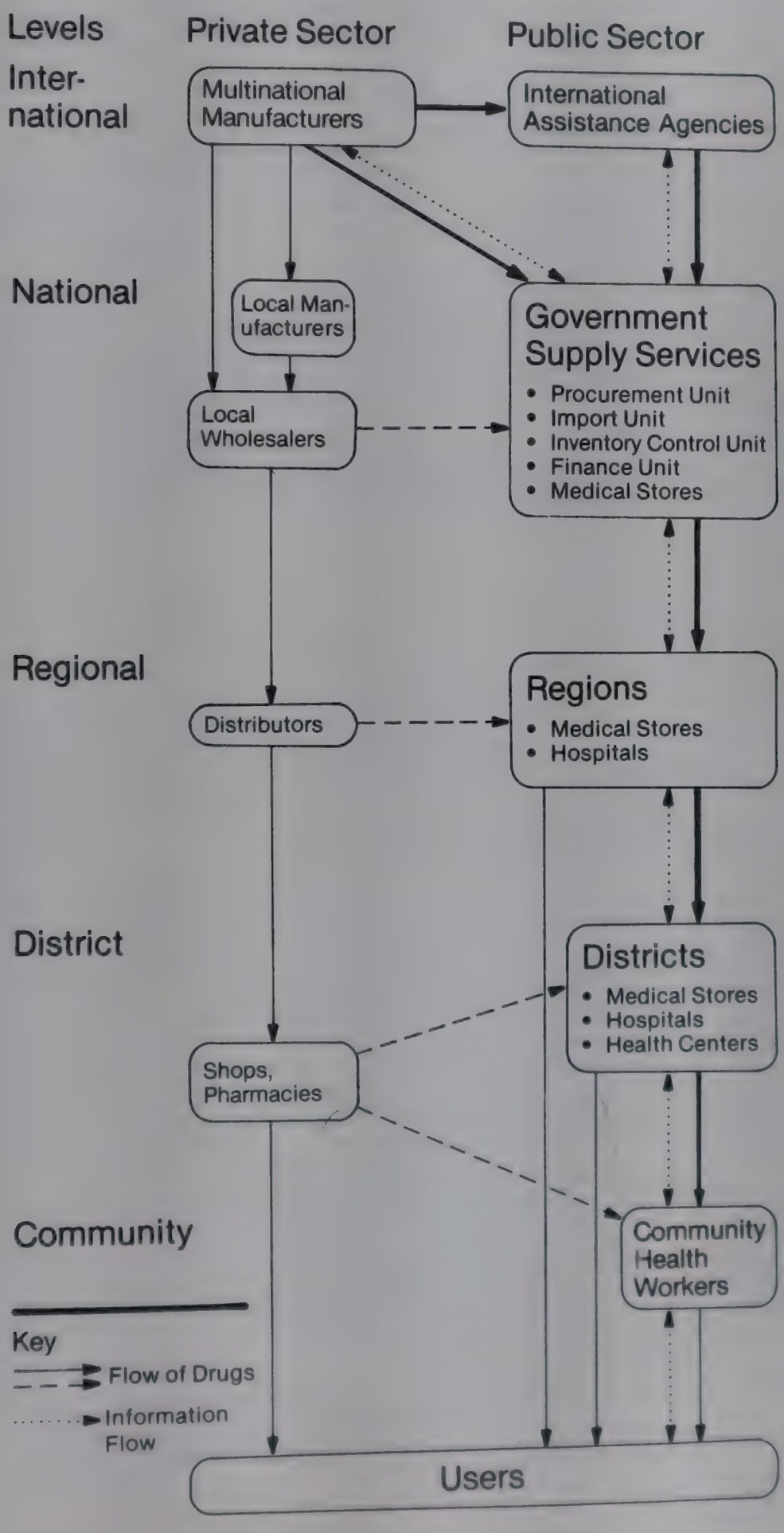
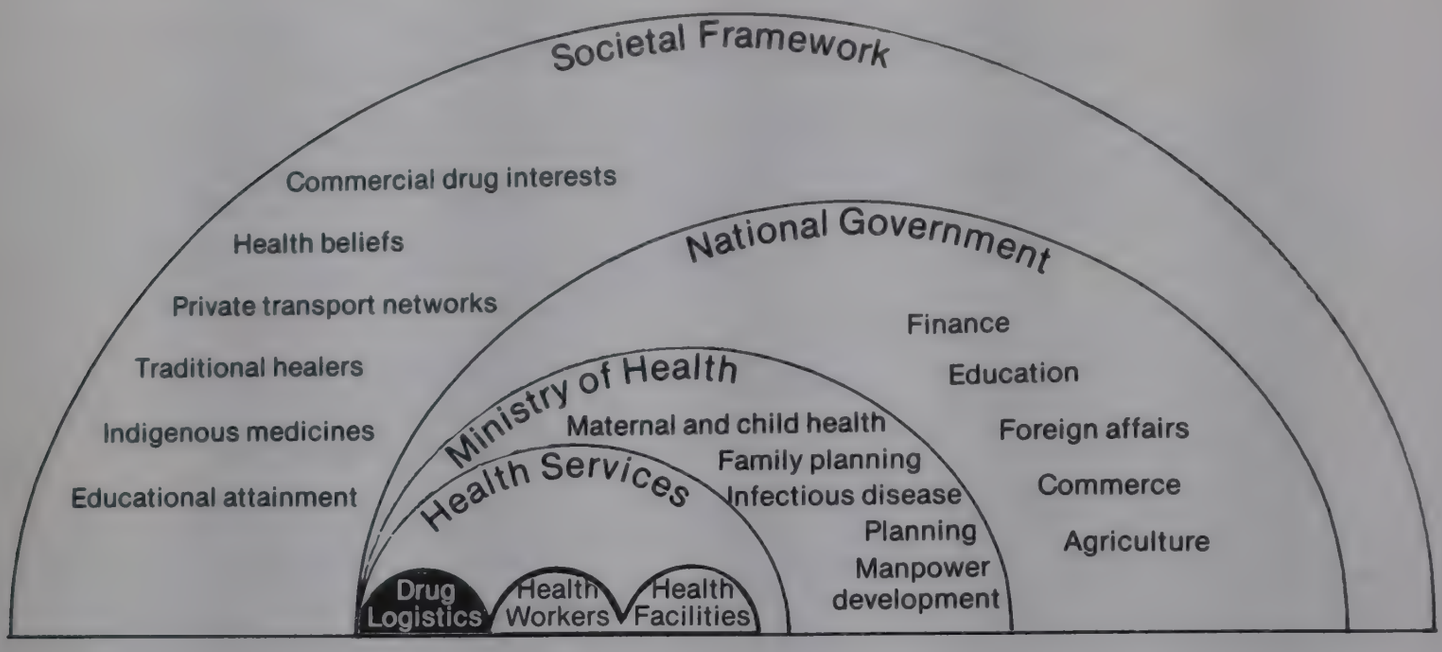


Figure I.B.3.

The Societal Framework of Drug Supply



In this context, government officials, technical advisors, and other decision-makers will find both allies and antagonists, who may be on separate sides of one issue, yet on the same side of another. This observation reflects, in part, the range of goals set for programs in pharmaceutical logistics. These goals may be related to health, economics, or national development.

Health-related goals include efforts to:

- make basic drugs available to the entire population;
- increase attendance at health clinics by increasing the credibility and acceptance of village health workers;
- assure the safety and efficacy of medicines provided in public programs;
- improve dispensing conditions, including labeling, packaging, and instructions to patients;
- rationalize the prescribing of pharmaceuticals; and
- promote correct use of medications by patients.

Economic goals may aim to:

- lower the cost of drugs to the government and the public;
- reduce foreign exchange drain for drug imports through wiser purchasing; and

- provide jobs in areas such as dispensing, prepackaging of drugs, and supply management.

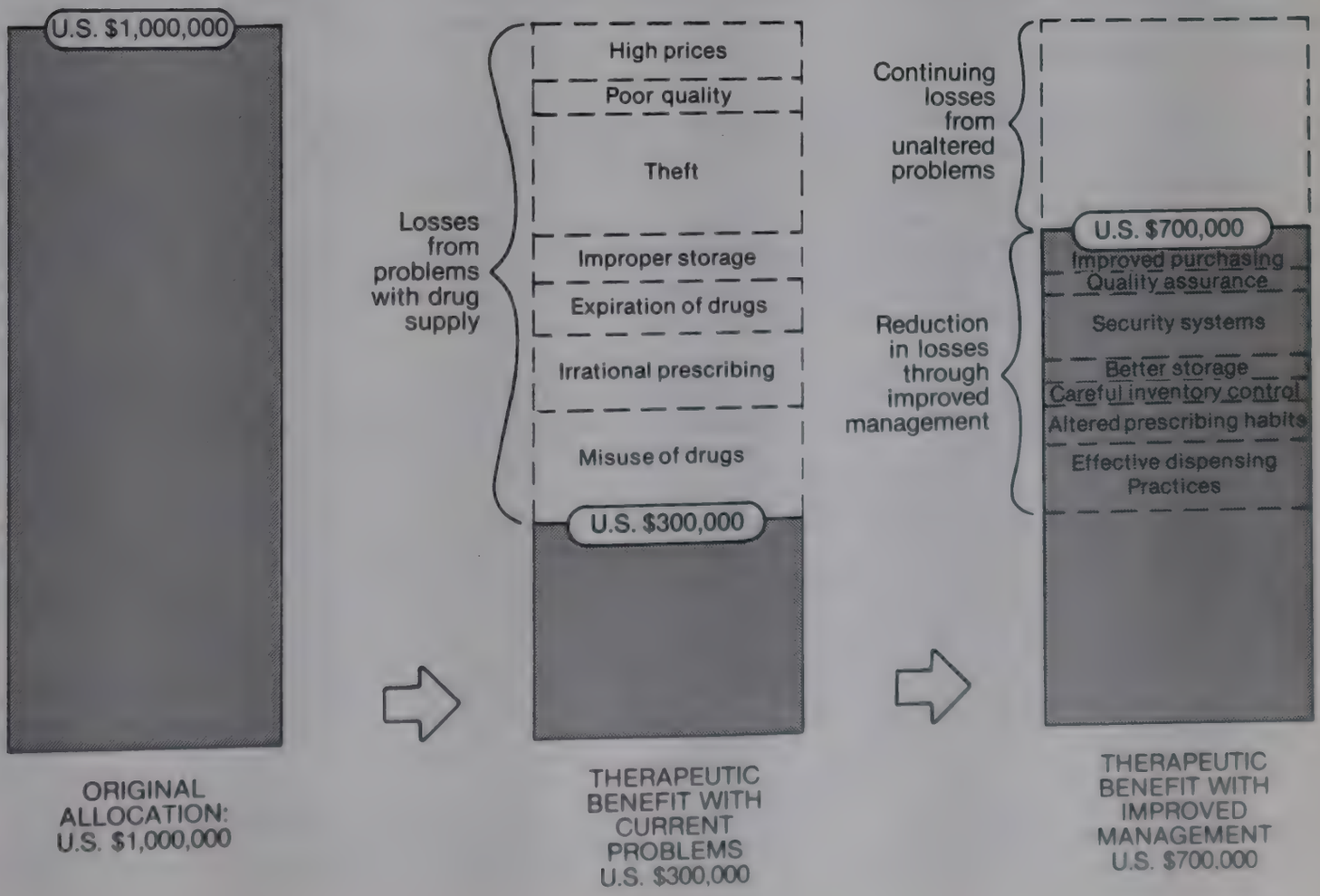
National development goals which may be addressed through a comprehensive approach to pharmaceutical logistics aim to:

- increase manpower skills in management, pharmacy, and medicine;
- improve internal communication systems; and
- establish a starting place for the evolution of industrial competence in packaging, chemical processing, and other production areas.

In most primary health systems, the potential for improving the supply process is tremendous. This reflects in part the magnitude of current inefficiencies and waste. Figure I.B.4. provides a typical example of a program in which a U.S.$1,000,000 annual expenditure on drug supply results in only $300,000 worth of therapeutic benefit to the patient. High prices, poor quality, theft, improper storage, expiration of drugs, irrational prescribing, and patient misuse result in losses totalling 70% of the original expenditure.

Figure I.B.4.

Problems in Drug Supply and Potential for Improvement



However, much can be accomplished with a great deal of effort, a moderate amount of know-how, and relatively little additional funding. Figure I.B.4. suggests that with specific improvements in management, much of the expected loss can be avoided. Improved purchasing, quality assurance, security systems, better storage, careful inventory control, altered prescribing habits, and effective dispensing practices can be implemented in most systems. The magnitude of benefit achieved in each of these areas will vary according to the extent of the current problems and the openness to change within different programs.

This manual aims to provide government officials, technical advisors, and other individuals involved in the supply process with the information needed to analyze their current situation, to identify problem areas, and to understand what options are available for making changes in the system. In responding to the question, "What can be accomplished?", the manual relies heavily on the accomplishments of developing countries themselves. These accomplishments are the best evidence of what is possible.

4. PLANNING AND IMPLEMENTING CHANGE: MANAGING THE BUILDING BLOCKS

To perform the functions of selection, procurement, distribution, and use, the logistics system must have certain resources. These resources, or structural components, include administration (organizational structure, policies, procedures), an information system, personnel, facilities, equipment and supplies, and finances. They form one of the dimensions of pharmaceutical supply indicated in Figure I.B.5.

The pharmaceutical supply system represented in this figure is a three-dimensional system. To perform each of the four major functions, all the components are required. At the same time, to a greater or lesser extent, each of the functions must be performed at all levels in the health system -- national, regional, district, and community. Effective management of all the components at each level and coordination among all of the functions is necessary for a smoothly operating system.

The components are the tools with which the work of the supply system is actually carried out. The nature and significance of each component can be summarized as follows:

Administration -- The organizational structure which determines lines of authority and responsibility, the policies which set the objectives and operational guidelines for supply activities, and the procedures which indicate the specific activities to be performed all fall under administration. Organizational structures are discussed in detail in both Chapter I.C. on planning, and Chapter VI.A. on organizing drug supply. Descriptions of policy options and various procedures for specific supply activities appear throughout the manual.

Information System -- Health officials, other decision-makers, technical advisors, and staff supervisors need reliable data on public health conditions, consumption rates, effectiveness of various drugs, and quantities of supplies

on hand. Critical decisions about what drugs to procure, what quantities to stock, and how to distribute them should be based on users' needs as well as consumption patterns. Unfortunately, the appropriate information is seldom well-organized and often unavailable. This may result in shortages of the most essential and surpluses of the least essential drugs.

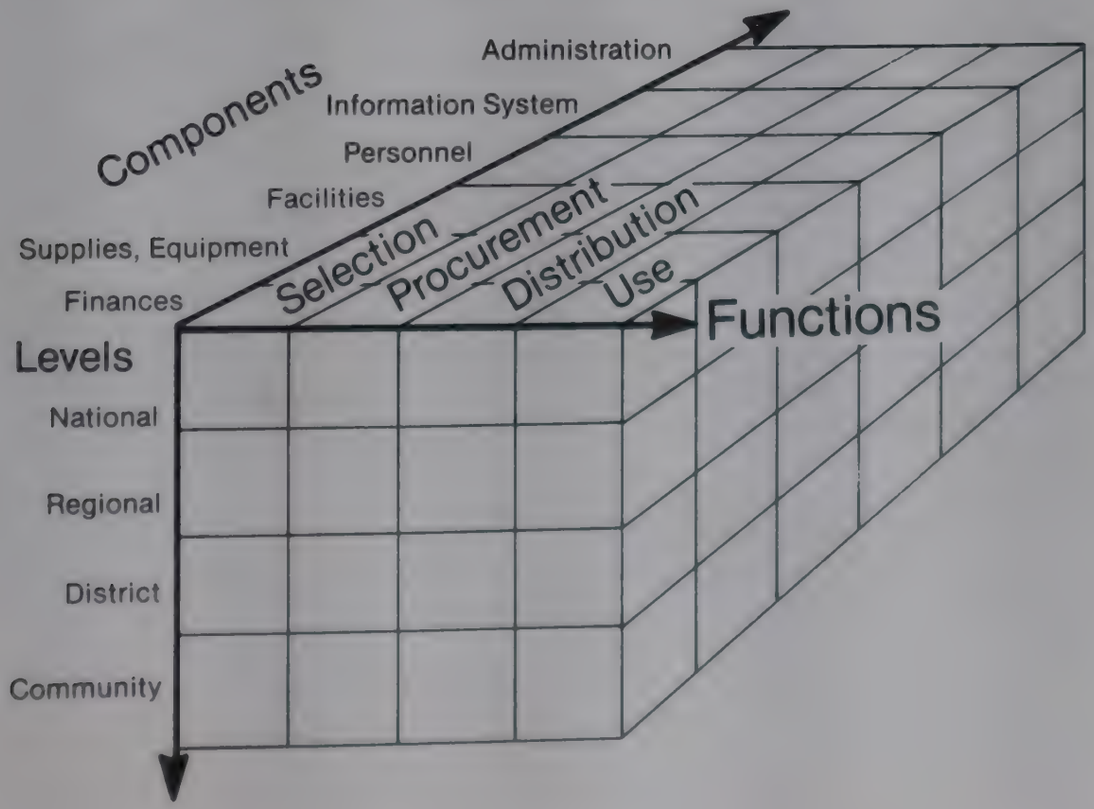
A major step in the solution of supply problems is to increase the emphasis on the information system and to train government personnel in collecting, transmitting, collating, and analyzing data. Information-related activities are discussed in many chapters, but receive particular emphasis in Chapter III.C. on supplier selection, Chapter IV.A. on the distribution cycle, Chapter IV.B. on inventory control, and Chapter VI.A. on organizing drug supply.

Personnel -- Capable, experienced, and adequately trained personnel are basic to the success of any organization. Specialized staff are required for each of the major functions of drug supply and their roles are described in the relevant chapters. Often these individuals can be trained on the job, provided that their job responsibilities are clearly defined and that specific training programs are made available to them. Chapter IV.D. is devoted to training needs and techniques appropriate for supply staff.

Facilities -- For many of the activities in the logistics cycle, simple but well-organized facilities suffice. However, for storage of pharmaceuticals, there are specific facility requirements which must be considered; these are discussed in some detail in Chapter IV.D. on storage.

Figure I.B.5.

The Dimensions of Pharmaceutical Supply



Equipment -- Vehicles, material handling equipment (hand carts, lifts, etc.), and such mundane items as file cabinets for supply records are all needed for the operation of the supply system. Such equipment is a variable but potentially large factor in the logistics budget, as much of it is imported But the expense of adequate equipment must be balanced against the costs of damaged and spoiled drugs from poor handling, emergency deliveries using commercial carriers when routine modes of delivery fail, and the health impact of irregular supply and frequent stockouts. The most vexing problem is that of acquiring and maintaining vehicles. These subjects are covered in detail in Chapter IV.E.

Finances -- The adequacy of all the preceding components is dependent in large measure upon the availability and management of financial resources. The funding of drug supplies is touched upon in the following section.

5. FUNDING: THE UNIVERSAL CONSTRAINT

A central inescapable fact is that health care is not free. To offer a service someone must pay. Many countries, however, espouse a policy of providing free drugs in public health programs. Perhaps this is because preceding governments in that country have done so; perhaps it is because of the impression that other countries do so. The unfortunate fact is that virtually no country is successful in providing free care, and everyone suffers. The cost of "free" drugs is scarcity, stockouts, and disillusionment. Ministry of health staff are dispirited by trying to provide services without resources, and the people are frustrated by receiving so much less than promised.

Ironically, people in even poor rural areas have been found to spend their own money on drugs, often the most valued health commodity. These expenditures may represent more per capita cost than governments could ever allocate. Recognition of this reality may be the only viable means of balancing drug supply and demand. A realistic solution may lie in the development of a creative partnership between government responsibility to organize the supply of basic pharmaceuticals, and individual responsibility to pay for what is needed and valued.

A careful review of financing policies is, therefore, a prerequisite for successful intervention. Financing is more fully discussed in Chapter III.E. of this manual.

SUMMARY

There are many reasons to be concerned about drug supply in primary health programs, the most important of which are that:

- drugs improve health;
- drugs promote trust and involvement in health services;
- drugs are costly;
- substantive supply improvements are feasible.

Logistics is the science of procuring, maintaining, and transporting supplies. The primary functions in the drug logistics cycle are:

- selection
- procurement
- distribution
- use.

Each of the functions is fraught with numerous pitfalls which arise because of poor management, unskilled staff, inadequate resources, and difficulties with medical practitioners and patients.

Despite the many pitfalls which are almost universally encountered, a great deal can be accomplished to improve pharmaceutical supply. Health-related goals, economic goals, and national development goals can be realized through improved drug supply mangement. Optimal use of available resources and cooperative public-private interactions are necessary for substantive, lasting improvements.

Planning and implementing changes in pharmaceutical supply requires wise management of the components, or building blocks, of a supply system. These components include:

- Administration
- Information System
- Personnel
- Facilities
- Equipment
- Finances.

Funding constitutes a universal constraint on drug supply programs. A policy of free drugs for all, espoused by many governments, is virtually never successful. Scarcity and stockouts are common, resulting in public disillusionment and dispirited health workers. Careful review of financing policies is a prerequisite for successful intervention.

CHAPTER I.B. REFERENCES

Bates, J.A.; Hartman, F.; O'Connor, R.W.; Quick, J.D.; and Rousselle, P.J.: Procurement and Use of Drugs: Managing the Process to Advantage. In Zatuchni, G.I. (Ed.), Vaginal Contraception: New Developments, pp. 325-335. New York: Harper and Row, 1979.

Gish, O. and Feller, L.L.: Planning Pharmaceuticals for Primary Health Care: The Supply and Utilization of Drugs in the Third World. Washington, D.C: American Public Health Association, 1979.

Institute of Medicine: Pharmaceuticals for Developing Countries. Conference Proceedings. Washington, D.C.: National Academy of Sciences, 1979.

Lane, N.S.: A Vital Link: Ensuring Supplies of Medical Equipment and Drugs Where Really Needed. WHO Chronicle 31: 404-407. Geneva: World Health Organization, 1977.

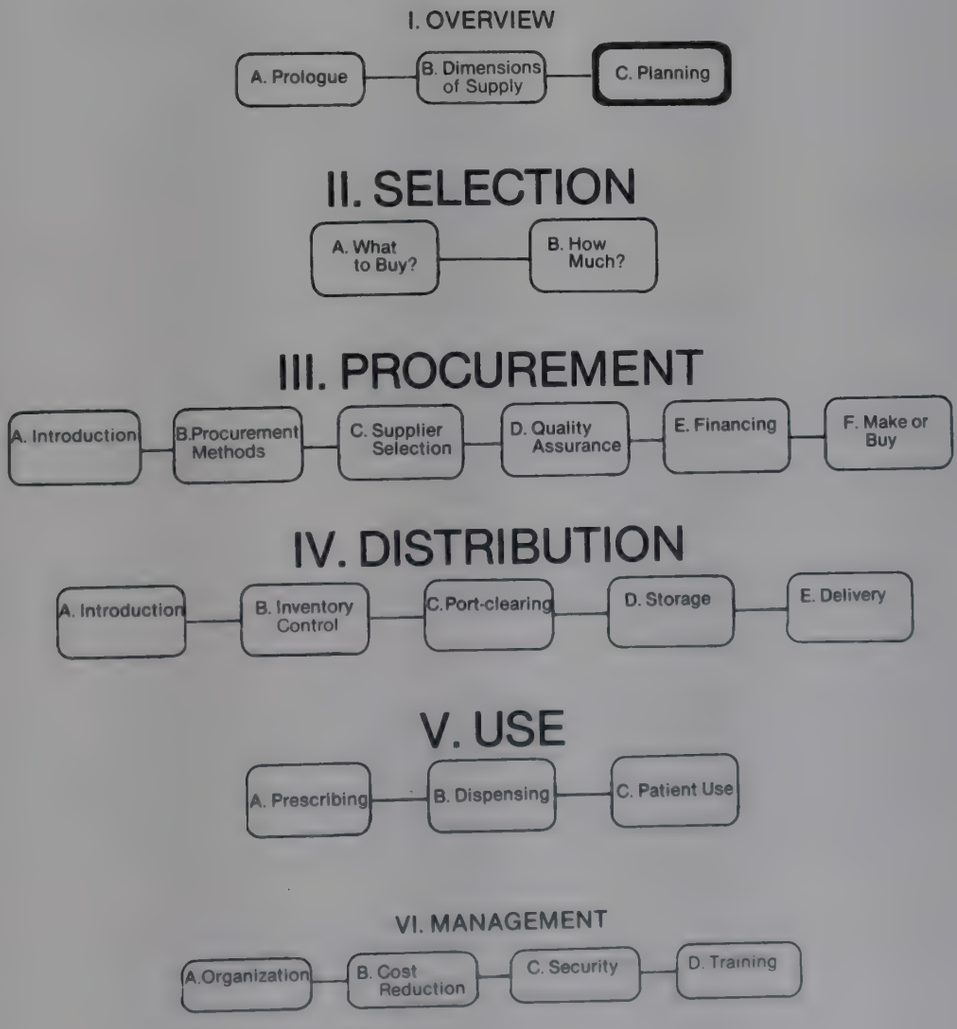
Segall, M.: Pharmaceuticals and Health Planning in Developing Countries. IDS Communication 119. Brighton, Sussex: Institute of Development Studies, 1975.

World Bank: Health Sector Policy Paper. Washington, D.C.: World Bank, 1975.

Yudkin, J.: Provision of Medicines in a Developing Country. The Lancet, pp. 810-812, April 15, 1978.

Chapter I.C.

Planning for Drug Supply



	Page
1. PLANNING MODELS	25
2. DEVELOP A PLAN	27
a. Establish a Logistics Planning Team	27
b. Define Goals and Objectives of the Health Sector	28
c. Establish Priorities	28
d. Describe Logistics Situation and Resources Available	29
Organizational Tables	
Description of Resources	
Flow Charts	
e. Identify Deficiencies in Logistics Process	35
Establish Operational Targets	
Problem Analysis	
f. Design Strategy for Improvement	35
Grouping Deficiencies and Proposing Changes	
Mini-Maxi Study	
3. DEVELOP AN IMPLEMENTATION STRATEGY	41
a. Implementation Issues	41
b. Prepare Detailed Implementation Schedule	42
c. Prepare a Budget	44
4. EVALUATE IMPROVEMENTS AND ADJUST PLANS	44
a. Internal Evaluation	44
b. External Evaluation	44
SUMMARY	46
REFERENCES	47

Planning for Drug Supply

Pharmaceutical logistics does not exist in isolation, but as a very important subsystem of the total health system that provides services to people in need. As noted in the preceding chapter, the health system itself is just one sector in the overall social system that exists in any country (Figure I.B.3.). The primary goal is to reduce discomfort, disability, and death through provision of health services at the community level. The logistics system exists to help achieve this goal by interrelating with the other support systems that share the same goal. In developing a plan for logistics system improvement, it is important to define the boundaries of the "system" broadly enough to include all the components that will have major impact on the success or failure of the plan.

1. PLANNING MODELS

There are 6 basic steps to developing a plan for logistics improvement that will ensure consideration of all these factors:

a. Establish a logistics planning team.

b. Define the goals and objectives for the health sector.

c. Establish priorities for program development.

d. Describe the logistics situation and the resources available.

e. Identify deficiencies.

f. Design strategy for improvement.

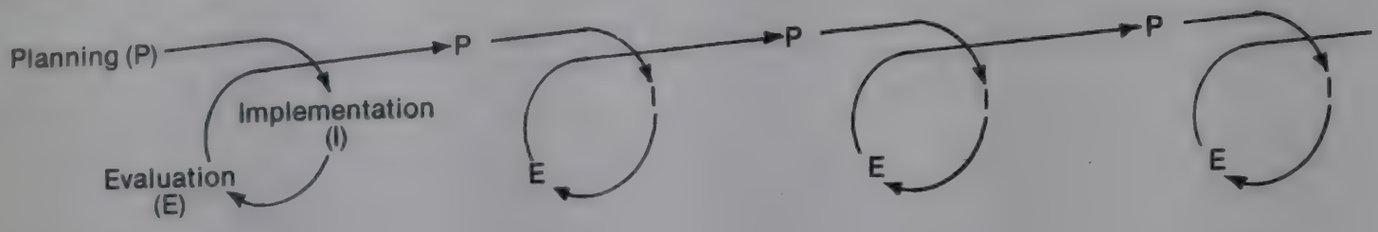
Once a plan has been established, a strategy for implementation must be developed; after changes have been implemented, the effect of these changes should be evaluated and the results of this evaluation used to adjust future plans. These three phases -- planning, implementation, evaluation -- are continually repeated to form the "iterative cycle of planning".

Figure I.C.1. illustrates two ways this cycle could work. In the first strategy the planning-implementation-evaluation model resembles a bicycle moving forward with cycles of equal size. This implies that the plan is designed for the entire logistics system, implemented, evaluated, and then adjusted as needed. Given the current state of logistics systems in most developing countries, up to five years may be needed to follow this strategy.

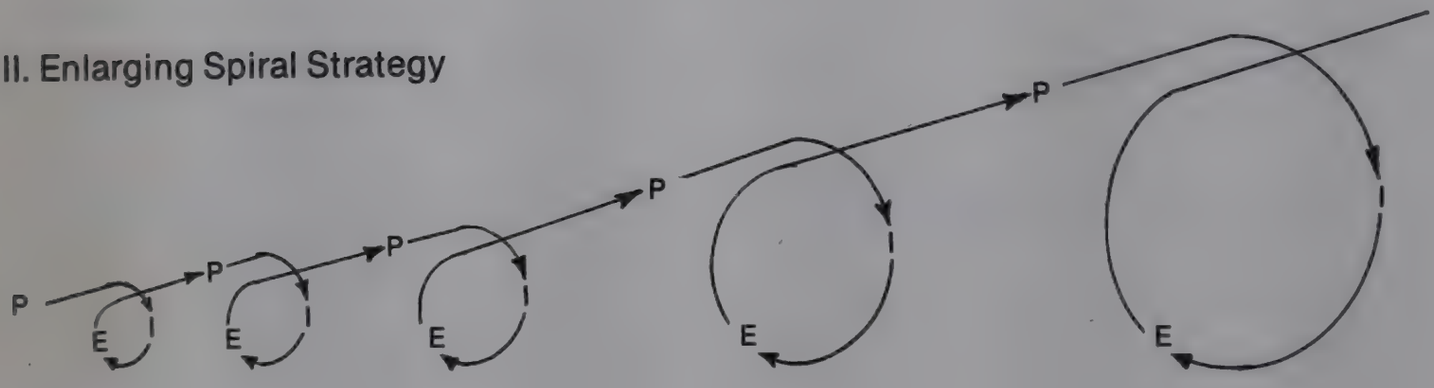
The second strategy resembles a progressively enlarging spiral. Initial planning cycles are quite small in time and scope. Implementation occurs in small increments that allow rapid evaluation and quick adjustment of plans.

Figure I.C.1.
Iterative Cycles of Planning

I. "Bicycle" Strategy



II. Enlarging Spiral Strategy



The experience gained is thus incorporated into subsequent cycles, and, although the planning cycles enlarge, this process minimizes the chance of making large errors and wasting scarce resources in the initial stages.

The basic sequence of planning-implementation-evaluation is the same, whether the bicycle or the enlarging spiral strategy is chosen. Experience suggests that the enlarging spiral strategy works best where resources are limited, where logistics improvements are intended for a specific vertical program, or for a regional project. The experience gained in this limited fashion can be progressively incorporated into larger national programs whenever the national commitment exists. The bicycle strategy works best when one is working with a national health service and resources are ample, often including funding and/or technical assistance from external donors. Substantial commitment on the part of the host government to this strategy is a primary prerequisite for success.

Subsequent sections of this chapter will explore each of the steps in planning, implementation, and evaluation in more detail.

ASSESSMENT GUIDE I.C.

Planning for Pharmaceutical Supply

- What are the goals and objectives of the health sector? Is logistics a major obstacle to health system improvement? What are the specific priorities for program development?
- What sectors outside of health have an impact on the logistics system? What is the current logistics situation and what resources exist within the system?
- Who should make up the planning team for logistics improvement? What administrative divisions/agencies/ministries should be represented? What policy support does the planning team need to support its efforts?
- What specific deficiencies exist within the logistics system that need improvement to help attain the goals and objectives of the priority programs?
- What recommendations can be made for improvement? Which implementation strategy will work best?
- What evaluation mechanisms need to be developed? How should the logistics process be adjusted based on evaluation?

2. DEVELOP A PLAN

a. Establish a Logistics Planning Team

This is the basic preparatory step for plan design. In this phase, it is useful for authorities in the health ministry and other involved ministries (planning, finance, foreign affairs, etc.) to do the following:

- Recognize that pharmaceutical logistics is a problem that needs joint planning for resolution.
- Assign personnel to work on the planning team, being careful to include top or mid-level managers from all the major ministries (planning, administration, finance, health). Technical advisers from external donors should also be a part of this team.
- Establish terms of reference including the goals and objectives of the logistics system.
- Establish a policy-making/supervisory authority for the planning team. In the case of small projects, this could be the Director-General of Health. In large projects involving external donors, a

technical coordinating committee should be established (if none exists) consisting of senior officials from all collaborating organizations or ministries. Cooperation at the policy-making level is essential to successful implementation of planned improvements.

The planning team is then responsible for all subsequent steps with periodic review by the supervising authority.

b. Define Goals and Objectives of the Health Sector

Improved logistics support is not an end in itself, but a means to realize certain goals in public health management. These goals vary from project to project, but in general they cluster around:

- Intervening to reduce morbidity and/or mortality (discomfort, disability, death);
- Expanding opportunities for preventive and/or curative medical care;
- Upgrading the quality of service in health care systems.

Specific activities need to be completed to achieve these goals. These can be expressed as objectives. Typical examples of such objectives include a targeted percentage increase in facility utilization, opening up a specified number of new facilities, or maintaining certain stock levels of pharmaceutical supplies at clinical outlets. Thus, the design for improvements in pharmaceutical logistics must point to these specific objectives.

Most developing countries have annual and/or Five Year Health Plans that outline specific goals and objectives. Where these do not exist, review of the health sector budget should give an indication of past priorities, although specific measurable objectives may be lacking. In some cases, it may be necessary for the planning team to interview senior officials or hold a workshop to establish concrete goals and objectives. This is most often the case when establishing a new project, and logistics planning is one component of the overall planning effort. If a new set of goals and objectives needs to be defined, this can be combined with the following step.

c. Establish Priorities

Once the health sector goals and objectives have been defined, it is important to establish priorities among them. Annual health plans will often list priorities, but at times they will need to be developed. The simplest way is to hold a workshop of senior ministry officials. Several techniques exist for establishing priorities through group process, such as the Delbecq Techniques for problem identification.* If a workshop is impossi-

---

* Delbecq and Vande Van, 1971.

ble, then the planning team needs to personally interview the policy-makers. It is not unusual to find conflicting priorities depending on who is interviewed. When this happens, the conflict needs to be openly discussed and some resolution attempted. If conflicts remain, then multiple "push-pulls" on the logistics system will inhibit its effectiveness.

Key questions need to be answered during this phase:

- Does the government emphasize integrated services or vertical projects? Should we plan for a unified logistics system, or will separate systems be developed for each project?

- Will this be a regional project or a national program? If regional, what plans will be made for national expansion?

- Which programs will be implemented first, i.e., where should the logistics system place its emphasis? Will nutritional supplements be used, and will they be a part of this logistics system? Will insecticides, pipes, and cement be included? Will the emphasis be on extension of coverage to rural areas, or will development of regional or district hospitals have priority?

- Will mobile teams be used for health service delivery, or will people come to fixed health centers?

- What emphasis is placed on the use of auxiliary and community health workers within the health system, and what are their specific functions?

- What priorities do external donors have for program development?

The initial response to these questions is often to say "We need them all -- we need immunizations and contraceptives, we need integrated basic health services and vertical projects, we need to supply hospitals and community health workers, etc." Although this may be the ultimate goal of the logistics system, it is seldom possible to do everything at once due to resource restrictions. Therefore, this priority-setting phase is critically important to the design of improvements.

d. Describe Logistics Situation and Resources Available

Simply defined, logistics is the management science of moving large amounts of supplies, according to schedule, to large numbers of people located in different places. In order to do this, the four major functions of Selection, Procurement, Distribution, and Use need to be addressed. A series of activities (Chapter I.B.) needs to be performed to complete each area, and each of these activities must be linked together and coordinated so that the logistics process flows smoothly. The administrative structure for coordination of the activities is usually divided into individual components, including personnel, facilities, and equipment.

An accurate description of the current logistics system(s), including all components responsible for the required activities, is needed before one can analyze deficiencies and recommend improvements. The description should be as

objective and nonjudgmental as possible. It has three parts: (1) organizational tables depicting the administrative hierarchy of the ministry or program in question; (2) a description of the resources available to complete each activity; and (3) flow charts showing the dynamics of the logistics process. There is some overlap in these parts, but, generally speaking, the organizational tables will focus on the distribution of components in the system, the descriptions of the resources available, and the flow charts on linkages between components.

The tables in this and subsequent sections are based on a Ministry of Public Health in Latin America. This organization provides a model for demonstrating analytical techniques suggested here.

Organizational Tables

An "official" organizational table, even if inaccurate and outdated, is usually available and is a good place to begin. It should not be assumed that the table is current, so the names and relative positions of departments, offices, and programs should be cross-checked with participants and outside consultants if possible. If no official table is available, the documentation of existing assistance projects can be consulted (and probably should be in any case). If no table can be located, it will be necessary to construct one from the beginning, relying principally on interviews with knowledgeable people.

Once a reasonably accurate table of organization is drawn, the next step is to indicate which components of the system perform logistics activities. It is at this point that relationships become complex. It may be that some tasks are not being performed at all, while others are divided between two or more components. In other cases, one component may be involved in more than one activity. For example, a warehouse is a facility primarily concerned with storage, but it also forwards information for purposes of forecasting needs and inventory control.

Next to each component should be indicated the task areas that that component is involved in. It is important to verify each component and to be aware of misleading names. For example, in one ministry studied, the Department of Planning is primarily concerned with policy matters, and forecasting supply needs is actually handled by other departments.

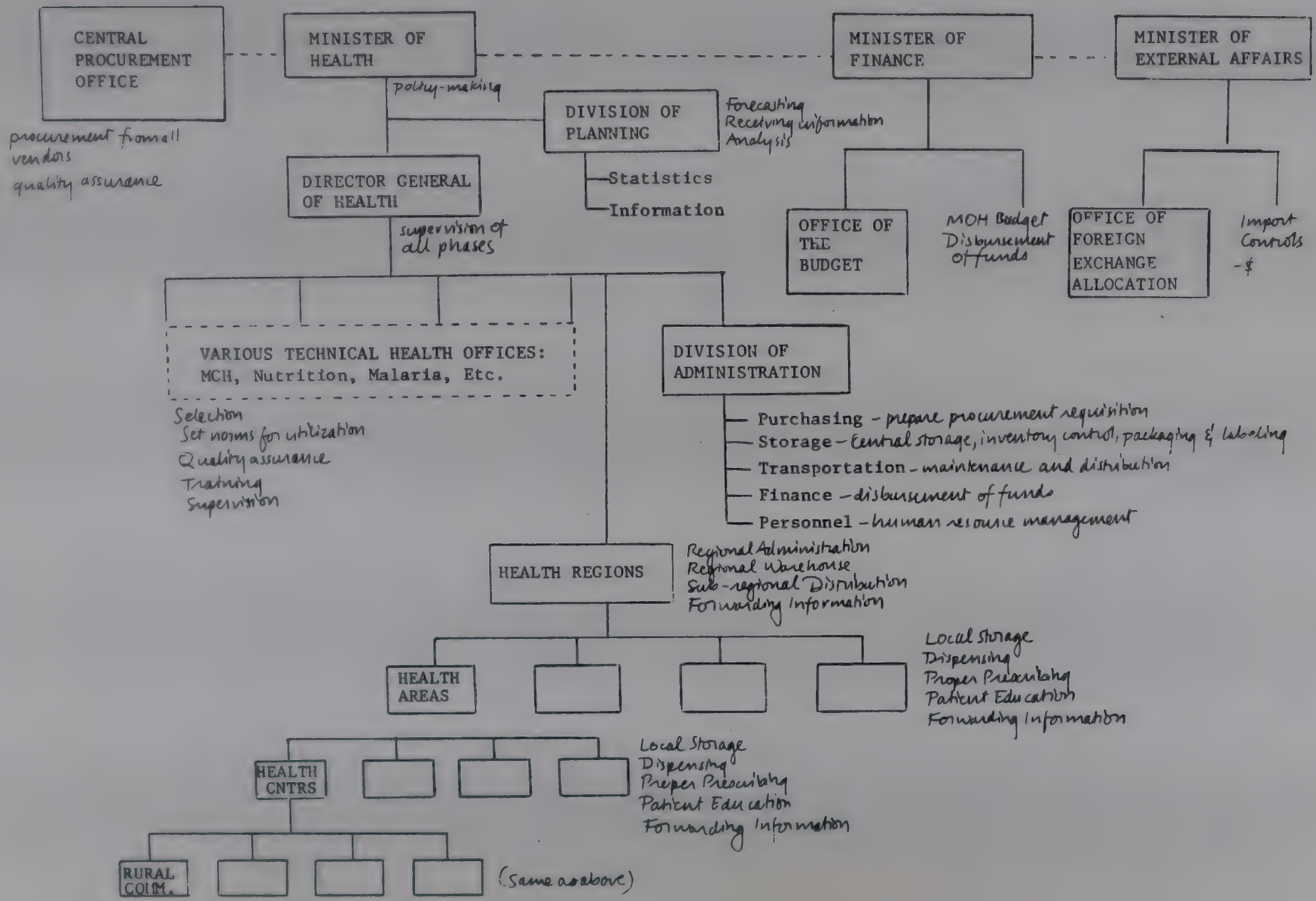
Figure I.C.2. is an example of an organizational table with logistics components identified. Again, it is important to expand the boundaries of the logistics system to include all the sectors that impact on the process. If the organizational structure is very complex, it may be necessary to break each division down into more detail on a separate sheet of paper.

Description of Resources

The resource descriptions should cover the personnel, equipment, supplies, and facilities which make up each component. Descriptions should include as many numbers as possible:

Figure I.C.2.

Organizational Table Describing the Logistics Process



- The number of people, their positions, responsibilities, and educational levels;
- Quantities and types of equipment and its state of repair;
- Capacities of facilities, especially regarding floor and office space, location, and utility.

When it comes time to make recommendations it must be known which components have the capacity to accept changes, and what type of changes should be implemented. An estimate of the workload is also important: the amount of work being done, the number of people doing it, and the equipment and facilities available. Some notion of whether a component is under- or overutilized will be important in setting targets, particularly with respect to the feasibility of planning additional work or responsibilities for a component.

When a component is complex, then a separate description of each of its departments may be desirable. An example would be a large warehouse with storerooms, plus accounting, receiving, and issuing departments. Charts or any visual aid which clarifies the internal workings of the component are useful for keeping the narrative clear.

Figure I.C.3. is a chart, listing, for each level identified in the organizational table, the resources available for the logistics process in primary health services. A separate chart should also be constructed for other priority programs, such as environmental sanitation or communicable disease control. This chart lists only a brief description for illustration. Actual resource charts require more extensive descriptions as outlined above.

Flow charts

The remaining step is to draw flow charts to illustrate the linkages between components of the system. The charts should show the sequence of activities in the logistics process as well as the linkages between components performing these activities.

Depending on the scope of the plan, the flow charts may be more or less complex. They are not ends in themselves. An overly complicated or cluttered chart is of little use to anyone. When working within one vertical program, complexity may not be a problem. It may be, however, if the problem embraces components scattered across a ministry's administrative system. This can be avoided by dividing the logistics process into discrete internal processes such as forecasting needs and budgeting, procurement, or requisition and delivery. Each of these is a multistep process, and drawing them separately minimizes the complexity of the charts. The flow charts should use exactly the same names which are found on the organizational tables.

Figure I.C.4. is an example of how the organizational table shown in Figure I.C.2. can be used to create a flow chart of the logistics process for requisition and delivery of supplies to health centers.

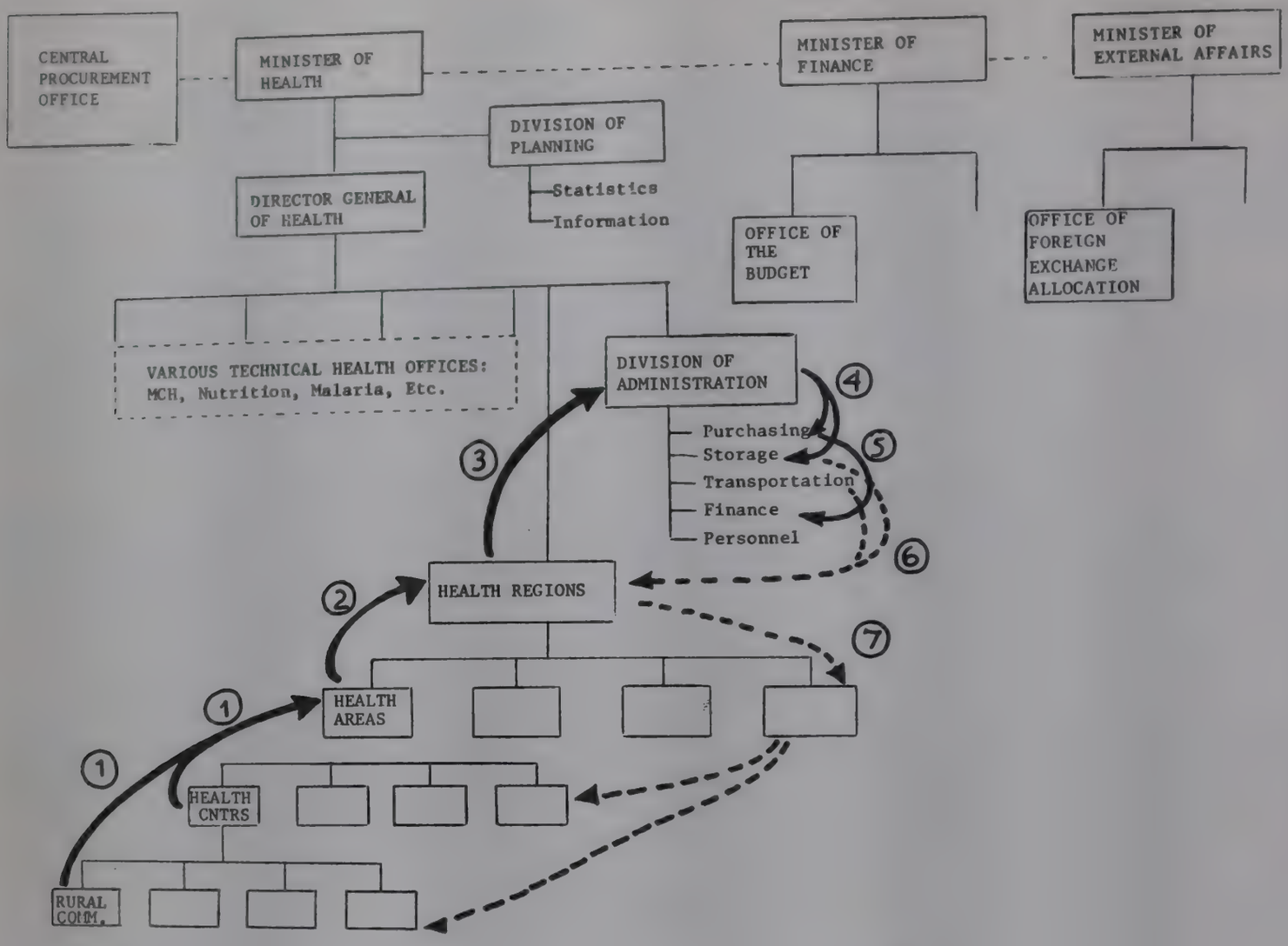
Figure I.C.3

Resource Description for Each Level in the Logistics System

LEVEL	RESOURCES			
Department/Office/ Establishment	Key Personnel	Expendable Supplies	Non-Expendable Supplies	Buildings
Administration Division: Purchasing & Supply Office	• Chief of Purchasing & Supply • Supply Planners • Civil Servant in charge of acquisitions	• Drugs • Forms for Programming • Forms related to purchasing process	• Calculators, typewriters	Main (Central) Warehouse with offices
Main (Central) Warehouse	• Main Warehouse Manager • Warehouse personnel • Drivers in charge of Supply Dispatch	• Drugs • Forms for Supply Control, Ordering and Distribution • Lubricants, fuel	• Shelves, platforms, jacks, calculators, typewriters, • (x) number of (x) ton trucks	New Main Warehouse needed; present one inadequate
Regional Hospital (Health Region Headquarters)	• Regional Chief • Civil Servant in charge of Supply Programming • Warehouseman • Drivers in charge of Supply • Laboratory Personnel	• Drugs • Forms for Programming • Forms related to Supply Control, Ordering & Distribution • Lubricants, fuel • Reagents, slides, shipping cartons	• Calculators, typewriters • Shelves, platforms; jacks, • 1 (x) ton truck truck • Laboratory equipment	Regional Storeroom inadequate
Area Hospital (Health Area Headquarters)	• Area Chief • Civil Servant in charge of laboratory • Warehouseman	• Drugs • Forms for Programming • Forms related to Supply Control, Ordering & Distribution Lubricants, Fuel Reagents slides, shipping cartons	• Calculators, typewriters • Shelves, platforms, jacks	Area Storeroom adequate (where
Health Center with Doctor	• Nurse auxiliary • Civil Servant in charge of laboratory	• Basic medicines, First Aid material • Forms for Supply Control Order & Dispatch process • Reagents, slides, etc.	• Instruments, medical bags; bicycles or motorcycles • Laboratory equipment	Small Storeroom
Health Center with Auxiliary	• Health Guardian • Health promoter • Vector Control Auxiliary	• Basic medicines, and First Aid materials • Forms for ordering • Reagents, slides	• Instruments, medical bags, bicycles or motorcycles	Shelves in health center
Community/ village	• Health Guardian • Trained midwife • Health representative • Volunteer collaborator for Vector Control	• Basic medicines, First Aid materials, forms for health guardian and midwife	• Instruments, medical bag, midwife kit	Shelves in home

Figure I.C.4.

Flow Chart of the Logistics Process



DESCRIPTION

① Rural communities and health posts send requisitions for supplies to Area Headquarters.

② Area Headquarters collates requests and sends supply requests to Regional Office. If Regional Office has supplies on hand, they are sent down to the Area. Where Area Office does not exist, they are sent directly to health posts / communities.

③ If supplies are not available at region, request forwarded to Division of Administration at Central MOH.

④ Division of Administration analyzes inventory reports & sends requests to:
- storage if stocks on hand
- purchasing if needs to be purchased & funds available.

⑤ Purchasing sends information to Finance to analyze budget expenditures to date.

⑥ If available, or after purchase, storage & transportation make arrangements to send supplies to regional warehouses.

⑦ Regional Warehouses then distribute to Areas, Health Centers or communities as needed.

PROBLEMS

- Information does not flow.

- Regional Offices do not all function well and requests are lost.
- Inventory information meager at central level and long delays result.
- Storage & transport are located in different facilities; communication & coordination poo
  50% break-down rate of vehicles.
- Finance does not have accurate, current budg
  data so cannot tell if request is ova-budget.

- Some Regional Warehouses very poor & do not serve as good intermediate distribution points.
- Likewise areas.

- Frequent absence of Health Auxiliary mean
  supplies arrive when health center closed and,
  thus, are returned to regional warehouse.

e. Identify Deficiencies in Logistics Process

Establish Operational Targets

The previous steps have established the objectives for the priority health programs and determined the resources available. In order to achieve objectives, minimal operational targets are necessary. To maintain constant stocks of pharmaceutical supplies, specific targets might include forecasting based on quarterly inventory reports from clinical outlets, doubling the number of scheduled deliveries, or holding stockouts to a certain level at the central warehouse. An analysis of the deficiencies of the logistics process (and subsequent proposals for improvement) should relate to these specific operational targets.

The targets should be realistic; e.g., it would not be wise to set a target of monthly deliveries to health centers when some health centers are two weeks' journey from the nearest warehouse.

Problem Analysis

A list of problem areas is generated by systematically examining the variables of activities, components, and information linkages in terms of their capacity for reaching the targets. This approach avoids preconceptions of what the main problems and solutions ought to be. The existing logistics system can be realistically assessed in terms of its capabilities for producing specific results, and various alternatives can be developed depending on the results desired and resources available.

Figure I.C.5. is an example of a problem matrix that is useful in identifying deficiencies in specific logistics activities. In addition to noting whether a component is adequate or inadequate, some estimate of what is needed to correct the deficiency and meet operational targets should also be given.

This task can be performed without outside assistance. However, it may be useful to involve an expert in pharmaceutical logistics who has done this type of problem analysis. Since public health officials may have lived with inadequate logistic systems all their professional lives, they may not be aware of all the potential problems within the system. In addition, this step begins to list some options for improvement, and it is helpful to work with people who have knowledge about a wide range of options and what is practical for implementation.

Problem analysis is the final and critical step before designing improvements.

f. Design Strategy for Improvement

In recommending changes, there are some considerations to be borne in mind. This guide has largely focused on techniques for identifying deficiencies within the logistics system. In addition to internal deficiencies which inhibit progress towards objectives, there are external obstacles such as budgetary or policy constraints which should be taken into consideration during the problem analysis. Planning improvements is a process of balancing

I.C.5.

Problem Matrix

Function	Activity	Administration			Information System	Personnel	Facilities	Equipment	Finances
		Policies	Organizational Structure	Procedures					
Selection	What Products?	Need policy to establish basic formulary	Need policy-making formulary committee to select products	Needs to be established	On therapeutic efficiency vs. cost	No formulary committee established	Adequate	Adequate	Adequate
	How Much?								
Procure-ment	Purchasing								
	Quality Assurance	Need policy to establish drug quality on entering country & at end point	Quality control lab or contract-out to private lab	To be established	Rapid feedback of quality analysis to managers	No personnel with adequate training to perform tests	Inadequate in-country laboratory facilities	Inadequate testing equipment	Too much spent for out-of-country testing
	Finance								
	Make/ Buy								

Distribution	Importation								
	Inventory Control								
	Storage	Adequate	Warehouses should be placed under Division of Admin., not Div. of Hospitals	Improved security, increased automation of requisition	More information on consumption	Inadequate space at central and regional warehouses	Understaffed - need at least 3@ central, 1@ each regional	Need forklift at central; more shelving at regional	More capital funds needed; operating budget adequate
	Delivery								
Use	Prescribing Practices								
	Dispensing Practices	Dispensing not recognized as special function	Clear line of authority	Adequate	Records well-kept by some, poorly by others	Drug dispensing primarily by untrained personnel	Cramped, unsanitary dispensing benches	Limited measuring cups and scales	Funds for drugs, rather than dispensers mean great drug losses by poor dispensing
	Packaging & Labeling								
	Patient Education/ Compliance								

internal deficiencies against external obstacles and making viable proposals for reaching objectives. "Viable" is a key word -- there is no point in recommending changes which run contrary to reality.

Strategies for improvement should consider the logistics system as a whole. The logistics process requires interaction between components of the system, and real improvement will invariably require multiple changes. Shoring up one component without taking into account the effect this will have on other components can cause unanticipated problems.

A final consideration is the amount of change a system will tolerate at one time. It will seldom be possible to completely redesign a logistics system. In some cases, seemingly irrational procedures have the weight of tradition behind them, and participants are reluctant to depart from them, especially when they do not perceive the underlying reasons for change. In other cases, proposed changes may violate an administrator's sense of control within his area of responsibility. In yet other cases, proposals may entail additional work for a group of employees who may resent interference which increases demands on them. Resistance to change for all of these reasons is common. If enough members of the system are sufficiently threatened, they can frustrate changes for improvements, even when the changes are logical and are backed by ample resources. Changes which are not necessary for achieving objectives should be avoided at this stage.

Grouping Deficiencies and Proposing Changes

Specific changes should be focused on those problem areas that will have the greatest impact on operational targets. Once deficiencies are identified, it may be necessary to modify targets and objectives in light of external obstacles, particularly resource limitations. When these indicators are settled upon, it is time to make recommendations for improvement. General suggestions such as "improve storage conditions" or "speed up the requisition process" won't do. Recommendation for improvement must:

(1) aim precisely to fix deficiencies noted in the problem analysis, and

(2) state the specific change necessary in order to meet expectations.

Precision and specificity are encouraged by ordering recommendations according to the activity that they affect and by categorizing the changes needed to eliminate each deficiency. Normally the changes will fall into one of the categories listed in the problem analysis:

- Changes in personnel -- modification of number, functions, placement, or training, or creation of new types of staff;
- Changes in facilities -- modification of size, design, placement, or equipment;
- Changes in administrative or operating policies;
- Organizational changes -- changes in organizational structures, responsibility, or focus of control;

- Procedural changes -- modification of procedures for record keeping, inventory, reporting, requisition, etc.

- Information changes -- changes in forms, requisitions, flow of information, manuals, automated processing, etc.

These categories are loosely ranked from easiest to hardest to analyze. Generally speaking, it is relatively easy to assess where more personnel are needed or which facilities need upgrading. It is somewhat harder to understand completely which policy or organizational structure will work better than those that currently exist. It is hardest to suggest precisely what new procedures should be instituted, or which forms should be eliminated and what new ones should be designed.

Officials and supervisory personnel (in collaboration with external advisors, if involved) can usually make good, concrete recommendations for personnel and facilities improvements. However, special studies and expertise are often needed to establish practical policies and organizational structures (e.g. what is the cost-benefit of a standard formulary and the organizational changes it implies?). Procedural and information changes usually require a detailed knowledge of the current logistics system coupled with substantial experience in implementation of successful systems in other countries with similar problems. This plan may require long-term technical assistance, although some countries may have enough "in-house" expertise to benefit from intermittent short-term consultancies. Requirements for technical assistance for implementation should also be identified in the final plan.

Mini-Maxi Strategy

When recommendations for improvement are considered, it is possible that they will exceed the resources available (or, at least, committed). In this situation, it is wise to develop a "mini-maxi" strategy that identifies the minimum changes needed to incrementally improve the logistics process, and the maximum changes needed to substantially improve performance.

Use of this strategy in a logistics plan developed for our example country is presented in Country Study I.C.1. Once again, a tabular format is helpful, listing each alternative, its cost, the justification, additional comments, and "mini-maxi" recommendations. In reality, this "mini-maxi" strategy was instrumental in stimulating donors to expand their financial commitment.

A separate table can be constructed for each of the components included in the problem matrix. However, it should be noted that procedural and information changes often require significant amounts of analysis, including long-term technical assistance. Thus, the complete logistics plan may develop in stages, with the first stage outlining recommendations for construction, commodity procurement, training of personnel, organizational or policy changes, and technical assistance. The second stage plan can then outline the more detailed changes needed in procedures or information after more intensive analysis.

Country Study I.C.1.

Mini-Maxi Strategy for Planning Improvements in the Logistics System

Alternative	Cost	Justification	Comment	Recommendations if funds limited to $6,000,000	Recommendations if funds substantially larger
Provide New Central Warehouse	$492,516	If the Project substantially increases the demand for supplies, the existing warehouse will become a serious bottle neck	If new central warehouse cannot be built, renting space is a feasible, but sub-optimal alternative.	Rent additional warehouse space	Allow $492,516 for new central warehouse
Provide Regional and Subregional warehouses	$28,000 each	Decentralization of storage is critical to the success of the project.	A total of 14 new buildings are now in place or under construction. 5 out of 7 Regional Headquarters have new warehouses, and 9 out of 33 health areas have them. Priority should be given to the Regional warehouses. As health areas are organized, each should receive a new warehouse. If this is financially impossible, then one area level warehouse serving 2 or more areas is feasible.	Allow $280,000 for 2 regional and 8 area level warehouses	Allow $728,000 for 2 regional and 24 area level warehouses
Provide motorcycles	$925 each	An outreach capacity for health workers is critical for the success of the Project.	The health center team consists of an auxiliary, a health promotor and an auxiliary for vector control. Not every health center will have all 3 workers. Where the number present is 1 or 2, providing 1 motorcycle is recommended; where all 3 workers are present, providing 2 motorcycles is desirable.	Allow $456,025 for 1 motorcycle each for 493 Health Centers.	Allow $622,525 for 1 motorcycle for 313 health centers and 2 motorcycles for 180 health centers.
Provide trucks	$10,750 each	Adequate vehicle resources at regional and subregional levels is critical to the success of the Project	If renovating the Ministry's fleet is not feasible or does not provide enough pick-up trucks (1 for each health area), then providing the necessary number is recommended.	Specific figures can not be given at this time	Specific figures cannot be given at this time
Refrigeration cold chain 1. Health center 2. Health area 3. Hospital	 $1,017 each $1,265 each $2,829 each	An adequate cold chain is critical to the success of the Project	It may not be necessary to provide many refrigerators.	1. Allow $501,351 for 493 health center refrigerators 2. Allow $89,815 for 71 health area refrigerators 3. Allow $36,777 for 13 hospital refrigerators	1. Allow $501,351 for 493 health center refrigerators 2. Allow $108,790 for 86 health area refrigerators 3. Allow $36,777 for 13 hospital refrigerators
Provide 1 person in technical assistance	$100,000 per year	The multiple activities necessary for designing and implementing an adequate logistic system require a specialist in this area, who is not already burdened with regular operational responsibilities	None	Allow $150,000 for 18 months technical assistance	Allow $200,000 for 24 months technical assistance

3. DEVELOP AN IMPLEMENTATION STRATEGY

Given the operational targets and recommendations for improvement developed in previous sections, the planning team must now develop a specific and concise implementation plan. Imagination and creativity are as important here as in other steps, and the planning team must remember to set the boundaries of the logistics system wide enough to include all relevant sectors.

a. Implementation Issues

Preparation of an implementation strategy depends on the answers to the following questions:*

(1) Who should be responsible for implementation? If the project is national in scope, if the Ministry of Health operates in a highly centralized fashion, if there is a department or division that is directly responsible for the project, or if it is of top priority, it may be necessary to assign responsibility for implementation to someone at a high level within the Ministry. It should be recognized, however, that such people cannot devote much time to new efforts. Decentralizing responsibility to the provinces or peripheral institutions offers the advantage of assigning responsibility to people who are directly involved with the implementation and most interested in its success.

(2) What sources of funds and manpower should be utilized for project implementation? It should be determined which staff are available to carry out the project activities in addition to their routine duties. It is sometimes possible to temporarily relieve people of routine tasks so that they can give their attention to specific project activities. When the necessary technical or managerial expertise is not available, it may be necessary to secure the services of a consultant. There also may be other projects competing for the same resources. If so, it may be advantageous to merge or identify with them, particularly for secretarial support, office space, supplies, and transportation.

(3) Are there potential problems of political, technical, or public acceptability? If so, the project staff may have to spend some time and effort in promoting the proposed strategies with legislative groups (to change laws), vested professional interest groups (to change policies), and other agencies (to obtain support and achieve coordination). All of this may require that the project have a high degree of visibility within the government and with the public. In other cases, there may be advantages in restricting publicity by burying the project within the activities of an existing program or service.

---

* Adapted from Bainbridge and Sapirie, 1974.

(4) How much flexibility is needed with regard to technical approaches, organizational structure, and sources of leadership? Most situations will require that the implementation approach be flexible enough to accommodate subsequent decisions or changes in strategies.

(5) In summary, what managerial approach should be used for implementation? Every organization has its strong and weak points. The planning team must assess, perhaps with the help of senior managers, where the strong and weak points of their organizations lie and whether the existing structure and staffing can absorb the additional amount of work represented by the implementation activities. Where the existing organizations (central ministry and decentralized service organizations) have (1) sufficient capable staff, coordination, and control procedures to apply effectively to new activities, and (2) the necessary influence over the political process and the attitude of health workers, professional groups, and the public, then these resources should be utilized for implementation. Normally, however, ministries of health and health services are taxed to their limit with routine administration and operations. Coordination and control may exist in certain special nationwide programs, but they are often deficient in more general services. Alternative approaches are then necessary.

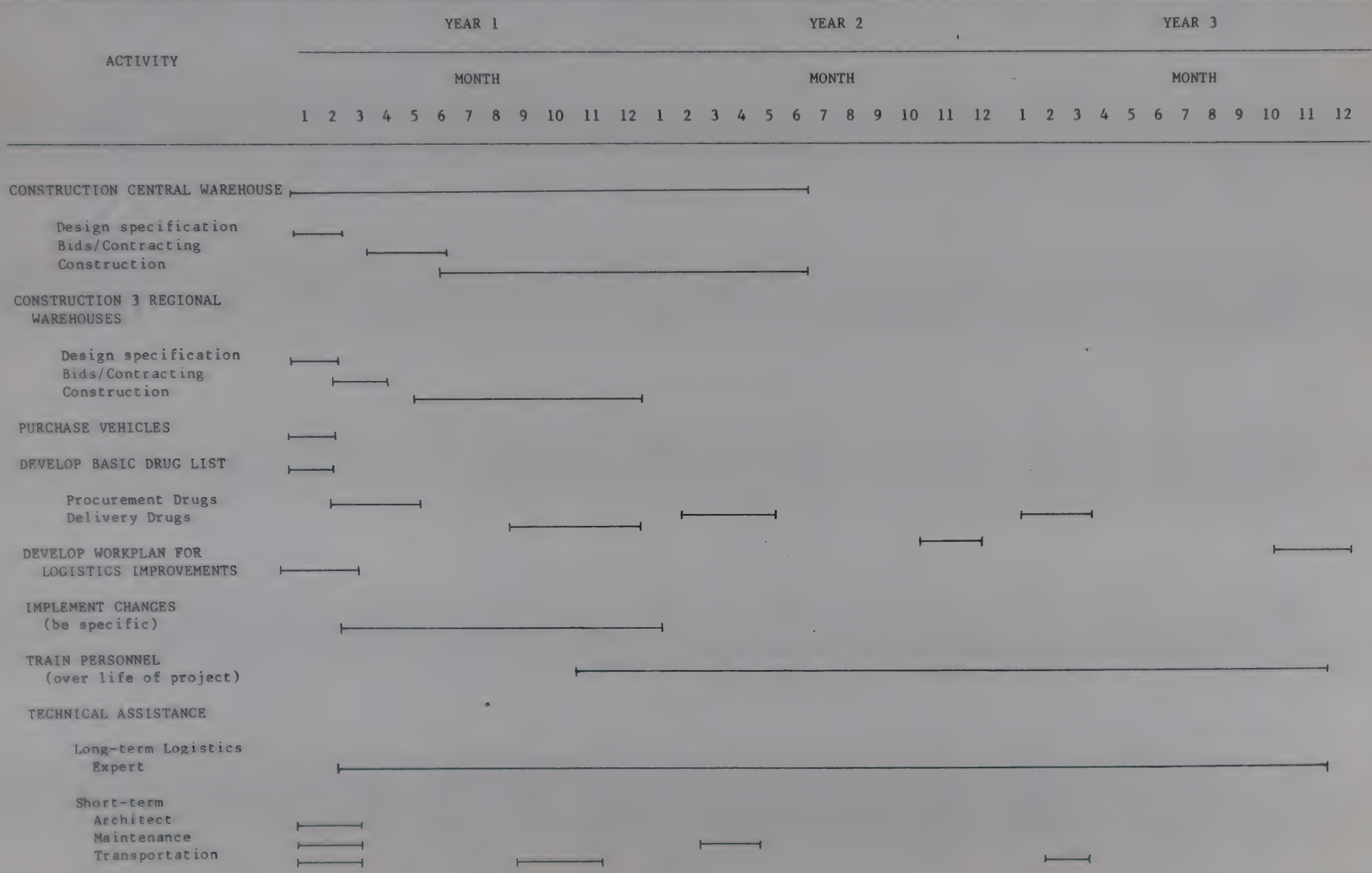
The project approach, which is one alternative, has certain features that may circumvent some of the obstacles to implementation. The project approach requires a separate administrative structure and personnel. This has the advantage of focusing attention and resources specifically on a circumscribed set of problems. It may have the disadvantage of not integrating the logistics process into the overall health system, and it does not strengthen the ministry as a whole.

All decisions concerning the implementation approach taken should be documented. This includes a brief description of the unit or organization that will be entrusted with the implementation, including the person to be in charge of the project, the full-time and part-time staff (and where they are from), and the reporting relationships with existing organizations. Care should be taken to delineate the scope of the project manager's responsibility, especially since some of the implementation activities for which he is responsible may well be carried out by staff over whom he has no direct authority. For other staff, there should be a description of their proposed activities and the times at which they will be needed. The project's most important working and control procedures should also be described.

b. Prepare Detailed Implementation Schedule

The next step is to draw up a detailed schedule for all the activities or tasks required to implement the plan. This is commonly done through using a Gantt or PERT Chart that identifies specific dates for initiation and completion of each activity identified above. An example of this chart is given for the recommendations previously presented (Figure I.C.6.).

Implementation Schedule for Logistics Plan



c. Prepare a Budget

The budget should include those costs directly related to improving the logistics system. It should present the total and annual costs of major expenditures by line item categories, and it is often helpful to separate them by host country and external donor contributions. The recommendation tables have previously identified costs for individual components; these can now be combined into line items, along with appropriate "mini-maxi" alternatives. Figure I.C.7. presents a budget matrix useful for identifying all relevant costs and inputs.

4. EVALUATE IMPROVEMENTS AND ADJUST PLANS

Evaluation completes the iterative cycle of planning-implementation-evaluation and leads directly to the next cycle of planning. For our purposes there are two types of evaluation to consider -- internal and external.

a. Internal Evaluation

This is the process by which managers evaluate the performance of the logistics system on a continuous basis. This is sometimes called process evaluation (i.e., evaluation of the logistics process). This involves developing a Management Information System (MIS) that provides regular (weekly, monthly, quarterly) feedback to managers at every level in all the required activities and allows prompt adjustment of inventories, deliveries, purchases, etc. These are then compared with the established operational targets to see if they are being met. A detailed system of performance monitoring as described in Chapter VI.A. requires trained staff and sufficient staff time, but it can be invaluable for internal evaluation purposes.

The MIS should thus be developed to measure the specific operational targets developed in a previous step. We should point out that a poorly functioning MIS is invariably found in poorly functioning logistics systems, and improvements in this area often require substantial development work and technical assistance.

b. External Evaluation

This is the process by which an evaluation team, not normally a part of the logistics management system, evaluates performance. This is most commonly done as part of an overall evaluation of a health program, and aims to measure the degree to which the program meets its specific objectives (i.e., reduction in morbidity and mortality). This is often termed impact evaluation, and the logistics system is evaluated to the extent that it contributes to the effectiveness of the health system. If objective morbidity/mortality indicators remain unaffected and it is found that needed drugs or supplies do not arrive where needed, then, obviously, the logistics system needs to be adjusted, even if the MIS shows operational targets being met. In this case, the operational targets will also need adjustment.

gure I.C.6

Budget Matrix for Logistics Plan

Category	Host Country*		Donor*		Total*	
	Development Costs	Anticipated Annual Operating Costs	Development Costs	Anticipated Annual Operating Costs	Development Costs	Anticipated Annual Operating Costs
taff						
onsultants						
ravel/Per Diem						
uition/ Education Costs						
acilities						
ehicles						
quipment						
xpendable Supplies (non-pharmaceutical)						
harmaceuticals						
ther Direct Costs (specify)						

If recommended changes exceed available resources, then budget categories should be further subdivided to reflect the minimum funding needed to incrementally improve the logistics process and the maximum funding needed to achieve all operational targets.

If the evaluation shows no change in health status, but drugs or supplies are arriving where needed, then, obviously, the health program itself needs adjustment. In this case, the logistics system functioned well but had little impact on the ultimate public health goal, and it should be adjusted to meet the needs of the adjustments in public health priorities.

Of course, on occasion, external evaluation shows significant reductions in morbidity or mortality, and that needed drugs and supplies arrived on time and were heavy contributors to the ultimate program success. In that case, we are entitled to a smile of satisfaction in knowing that our plans have produced concrete benefits. The smile should last only until we find other unmet needs that require additional plans.

SUMMARY

Planning, implementation, and evaluation are the three phases which continually repeat to form the "iterative cycle of planning."

There are six basic steps to planning for improvements in the drug supply system:

(1) Establish a logistics planning team.
(2) Define the goals and objectives for the health sector.
(3) Establish priorities for program development.
(4) Describe the logistics situation and the resources available.
(5) Identify deficiencies.
(6) Design strategy for improvement.

In recommending changes in an already-existing system, it is important to consider external obstacles such as budgetary or policy constraints, the interrelationships within the logistics system, and how much change the system will tolerate. Recommendations must be precise and specific.

An implementation strategy should address the following issues:

(1) Who is responsible
(2) What funds and manpower are available
(3) Potential political, technical, or acceptability problems
(4) Flexibility of the approach
(5) Determination of the overall managerial approach.

Evaluation should be internal (performance monitoring of the logistics process) and external (evaluation of impact, whether program meets its objectives). Evaluation results lead to the next cycle of planning.

CHAPTER I.C. REFERENCES

Bainbridge, J. and Sapirie, S.: Health Project Management. Geneva: World Health Organization, 1974.

Delbecq, A.L. and Vande Van, A.: A Group Process Model for Problem Identification and Program Planning, Journal of Applied Behavioral Science (7):466-92, July-August 1971.

Hornby P. et al: Guidelines for Health Manpower Planning. Geneva: World Health Organization, 1980.

McMahon, R. et al: On Being in Charge - A Guide for Middle-Level Management in Primary Health Care. Geneva: World Health Organization, 1980.

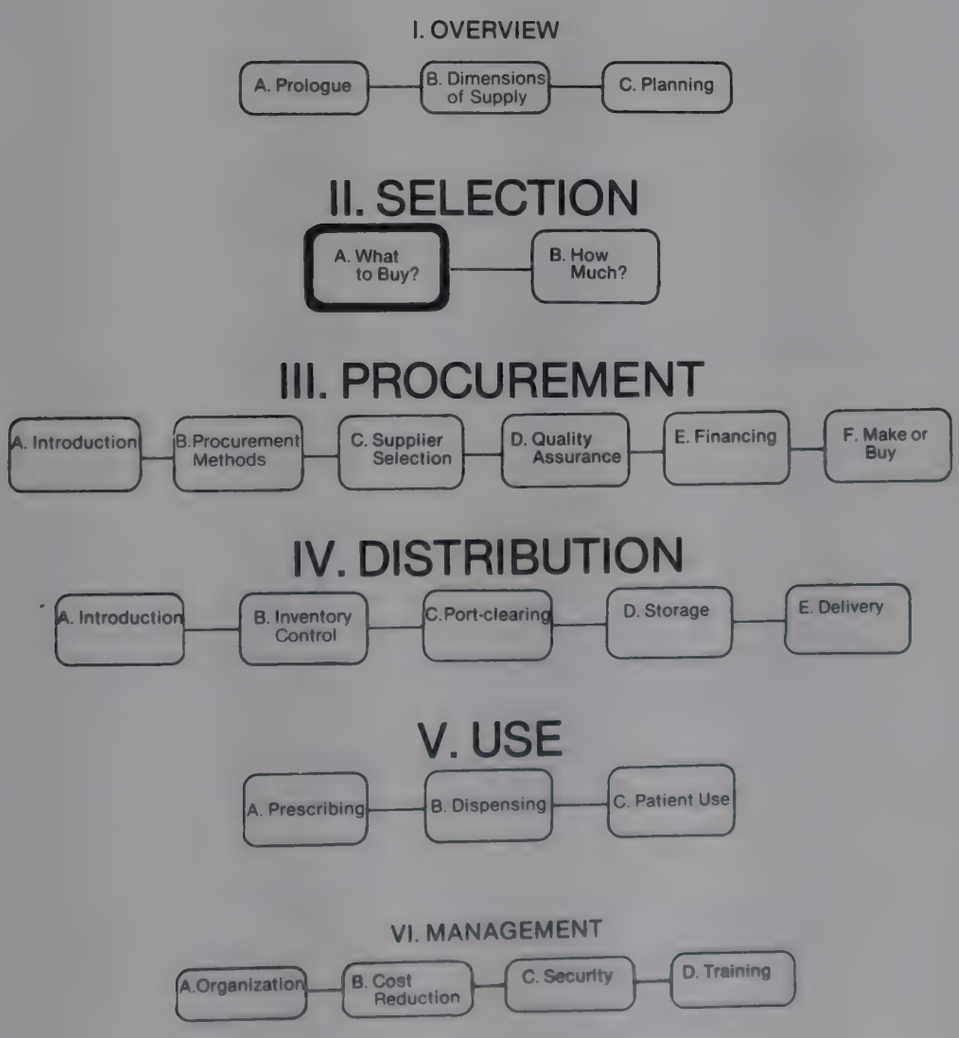
Segall, M.: Pharmaceuticals and Health Planning in Developing Countries. IDS Communication 119. Brighton, Sussex: Institute of Development Studies, 1975.

U.S. Department of Health, Education, and Welfare: Guidelines for Analysis of Pharmaceutical Supply System Planning. DHEW Publication No. (PHS) 79-50086. Rockville, MD: U.S. DHEW, 1979.

World Health Organization: Application of Systems Analysis to Health Management. Geneva: World Health Organization, Technical Report Series 596, 1976.

Chapter II.A.

What to Buy: The Selection of Drugs



		Page
1.	THE IMPORTANCE OF DRUG SELECTION: Why Be Selective?	51
2.	THE SELECTION PROCESS: Who Should Make the Selections?	54
3.	SELECTION CRITERIA: How Should Drugs Be Selected?	57
	a. Selection Guidelines	57
	b. Drug Nomenclature: What are "Generic Drugs"?	59
	c. Multiple Dosage Forms	60
	d. Local Remedies	60
	e. Formulary Structure	62
	f. Level-of-Use	62
	g. Information Resources	64
4.	GAINING ACCEPTANCE OF AN ESSENTIAL DRUG LIST	64
SUMMARY		66
APPENDICES		
II.A.1.	Information Sources of Value in Drug Selection	67
II.A.2.	Example of a Drug List Structured by Therapeutic Category and Level-of-Use	72
II.A.3.	WHO Revised Model List of Essential Drugs	74

What to Buy: The Selection of Drugs

Pharmaceuticals may comprise up to 40% of the health care budget in developing countries, yet large portions of the population frequently lack access to even the most essential drugs needed to prevent or treat prevalent diseases. The limited funds available for developing countries are frequently ill-spent on ineffective, duplicative, or unacceptably dangerous drugs. Funds are often wasted on nonessential drugs which are used inappropriately. Pharmaceuticals have potential for great benefit, but their economic impact is substantial. Therefore, the extent to which drug selection decisions facilitate the pursuit of rational therapy is a matter of considerable importance.

The development of a list of essential drugs and a rational total formulary for public health programs represents the major vehicle by which concerns for relative drug safety, efficacy, and economy may be brought to bear on the prescribing process. There are two primary advantages of a formulary or standard drug list:

(1) Therapeutic gain -- The quality of drug utilization, management, information, compliance, and monitoring is improved. Medical practitioners have a small, but complete list of drugs and they should have more knowledge about each of these drugs.

(2) Economic and Administrative gain -- The number of drugs to be purchased, stored, analyzed, and distributed is reduced. Bulk discounts are possible. Inventory costs are reduced.

Thus, the rational selection of an essential list of drugs optimizes drug therapy, assures relative safety and high quality, and reduces administrative costs associated with duplicative products.

1. THE IMPORTANCE OF DRUG SELECTION: Why Be Selective?

The multiplicity of pharmaceutical drug products available and the frequency of new discoveries in the field of medicine, make it difficult for the physician, medical auxiliary, practicing pharmacist, and other health care providers to be up-to-date and judicious in their selection of drugs. The variety of drug products available in some countries may include up to 80,000 products.

As many as 70% of the pharmaceuticals on the world market today represent duplicative, "me-too", or nonessential products. Many are minor variations of a prototype drug and offer no therapeutic advantage. Other drugs represent suboptimal choices of treatment because of high toxicity relative to their therapeutic benefit. In some cases, drugs are newly released with insufficient information of efficacy or toxicity. Finally, many, if not most, of these new products are for therapeutic indications not relevant to the basic needs of developing countries.

04700

COMMUNITY HEALTH CELL
LIBRARY
AND
DOCUMENTATION

ASSESSMENT GUIDE II.A.
The Drug Selection Process

- How many different drugs are available? What is the range of drugs currently available? Are there "duplicate drugs" -- many different drugs all of which serve the same purpose? Are there combination drugs for problems which could readily be treated with single drugs?

- How are the drugs selected? Is there a formalized process or is it informal? What criteria are used? Is cost a factor?

- Who selects the drugs and other pharmaceutical products for public health programs? The individual practitioner? Local health districts? Hospital pharmacists or therapeutics committees? A procurement clerk at the national level? A national committee? A physician? A pharmacist?

- Are drugs bought by their medical (generic) name or by their commercial (brand) name? Do pharmacists and medical practitioners understand the difference between generically-named drugs and brand name drugs?

- Are traditional medicines and local remedies available in government health programs? If so, how are they selected for inclusion?

- What kinds of drug information are available? Is the information up-to-date and unbiased? Do pharmacists and medical practitioners know where to look for information about drugs?

All of these factors serve to confuse the drug selection process of the already overburdened health care practitioner. With so many different drug products, it is difficult to be up-to-date with relevant prescribing information on each. Such a variety of products available also contributes to inconsistent treatment of disorders by health practitioners within the same health care delivery system.

On the level of procurement, purchasing power is significantly diluted by the large number of duplicate and nonessential drug products. Emphasis on a reduced number of drugs, on the other hand, markedly improves the efficiency of the entire pharmaceutical system. A reduced drug list allows the purchaser to concentrate on obtaining volume purchase prices from distributors and manufacturers. Quality control analysis can be performed more easily on a limited number of drugs. And inventory costs in terms of storage, record keeping, and personnel are directly related to the number of different drug products within the inventory.

Distribution is also greatly facilitated and simplified with a reduced number of products. Practitioners are better able to gain familiarity with the drugs they use and thus can dispense more accurately and more appropriately. And finally, patients are more likely to be treated with drugs of choice because health care personnel can be more efficiently provided with needed drug information.

An essential list of drugs is the cornerstone of any program to improve the pharmaceutical logistics process. It is the first step in rationalizing the use of drugs. Figure II.A.1. summarizes the steps involved in developing a government formulary.

Figure II.A.1.

Ten Steps to Developing a Formulary

Step 1: Obtain support for an essential list of drugs

- a. Within the Ministry of Health
- b. From the organized medical community
- c. Among local health care workers

Step 2: Establish Drug Selection Committee with appropriate representation

Step 3: Gather and analyze information on

- a. Prevalent morbidities
- b. Drugs available
- c. Patient characteristics (age, sex)
- d. Types of health care personnel at each level
- e. Local manufacturing activities
- f. Existing drug lists
- g. Pharmaceutical logistics problems

Step 4: Make decisions regarding

- a. Structure of formulary
- b. Format of formulary
- c. Criteria for selection

Step 5: Select drug products

Step 6: Include prescribing information

Step 7: Have draft reviewed by

- a. Nationally recognized specialists
- b. Local health care personnel

Step 8: Undertake educational campaign for

- a. Practicing health care personnel
- b. Patients

Step 9: Promulgate regulations

Step 10: Conduct annual update of formulary

2. THE SELECTION PROCESS: Who Should Make The Selections?

There are many approaches to the drug selection process, some of which are described in Country Study II.A.1. In some countries, a single official selects the drugs for the procurement list, while in others, committees are formed to accomplish this task. A third approach involves using a pharmacology consultant from inside or outside the country to prepare a draft list of essential drugs, which can then be reviewed and approved by a committee of local physicians and ministry personnel. For most countries, drug selection by committee is practical and preferable. It minimizes the opportunity for private interests to influence the decision-making process. Further, the judicious selection of committee members with relevant backgrounds and previous experience can facilitate the rational selection of drug products.

The selection of drugs for the basic list can be done at the national level, or autonomously by regional or local officials. An advantage of national level selection is the improved efficiency and economy of central procurement that is thus feasible. Regional and local selection, on the other hand, allows for the consideration of local differences in drug prescribing and use, and thus more appropriate purchasing, which centralized selection does not allow. In larger countries, regional selection and procurement may also be the most economically efficient system.

The lack of coordination of local, regional, and national needs is a common problem, and results in drugs sitting unrequested in central warehouses until they decay or pass their expiration dates. One resolution to this problem is to include regional or local physicians and ministry officials on the committee that selects the drugs to be purchased at the national level.

The greatest efficiency is possible when drug selection is coordinated with other activities in the supply process. This can be partially achieved by the makeup of the drug selection committee: it might consist of representatives from the Ministry of Health, the purchasing department, and regional and local health facilities, a pharmacologist, an internist, an infectious disease specialist, a pediatrician, a pharmacist, a hospital director, and other specialists as needed.

Committee members should serve for several years with staggered terms, so that the committee retains some experienced members each year. Ideally, committee members should not have work relationships with any drug manufacturer or distributor, nor be related to any person who does.

The drug selection committee should meet at least annually to update the essential list of drugs. Their decisions as to changes in the list should be supported by well established criteria. Use of a Formulary Revision Form (Figure II.A.2.) may facilitate rational additions and deletions. As the form requires a certain amount of effort on the part of the petitioner, it may reduce requests for items not really needed.

Country Study II.A.1.

The Drug Selection Process in Individual Programs

Guatemala -- A therapeutic formulary was developed for the Guatemalan public health system with assistance from an independent health care group. This formulary addressed two needs: 1) to identify a basic list of drugs, representing a rational approach to treating the country's prevalent morbidities, and 2) to provide accurate therapeutic information (indications, dosages, contraindications, and adverse effects) for each drug in the formulary.

The methodology employed included: (a) a review of the prevalent morbidities; (b) on-site evaluations of health care facilities and workers; (c) selection of drugs and therapeutic information for the formulary based on (a) and (b); (d) assignment of level-of-use designation for each product -- taking into account the types of patients to be treated and health care workers' training; (e) review of the formulary by prominent physician specialists within the public health system; (f) formation of a multidisciplinary formulary committee; and (g) presentation of the formulary to the Minister of Health, leading to its promulgation into law.

The formulary contains a list of "first-line" and "second-line" pharmaceuticals and eliminates duplicative, dangerous, or ineffective products. This approach pared down the original Cuadro Basico from 3,000 to 300 drug products. (1978)

Costa Rica -- Drug supply within the health program of the Social Security Fund is coordinated by a team of pharmacists. Drugs are selected by the Pharmacy Committee, consisting of a general surgeon, an internist, a pediatrician, an obstetrician-gynecologist, a pharmacist, a representative from the National Labor Union, and the Chief of the Social Security Fund drug program.

The 850 items listed in the first Social Security Fund Formulary list were selected by the Pharmacy Committee on the basis of recommendations from various specialists, review of lists from other countries, and reference to texts of pharmacology and therapeutics. The Formulary divides drugs into General, Pediatric, Medicines for Hospital Use, Dental Medicines, and Emergency Medicines and Antidotes. This list serves as the basis for a purchasing system which supplies the hospitals and out-patient departments that serve the majority of the Costa Rican population.

Additions to or deletions from the list are made on the basis of recommendations from the hospital pharmacy committees. Because it is an honor to be on these committees, it is usually the more successful and more secure staff members who participate. It is believed that this composition limits the likelihood of commercial influence. (1978)

Haiti -- In a recently initiated rural health program, the drug list for health workers was developed from mortality and morbidity information. After determining the types and frequencies of treatable diseases, therapeutic guidelines were established and, from these, a list of necessary drugs and quantities was developed. The principles used to select the drugs were as follows: (1) choose the minimum number of drugs to treat the most important diseases identified by epidemiological study of the target population; (2) use only generically named drugs; (3) limit dosage forms of each drug to only those absolutely necessary; (4) categorize the list according to level-of-use. The list was developed by an independent health management group in conjunction with specialist consultants and Ministry of Health officials. (1980)

Norway -- Currently, Norway has registered only about 800 active ingredients in 1,800 preparations (brands, combinations) and 4,800 dosage forms and package sizes. The rationale for limiting the number of drugs is not an economic one, but a quality-of-care one: it is believed that rigorous restriction of drug availability will promote rational drug therapy and avoid confusion among the prescribers, the patients, and the distribution services. Norway has been able to maintain this restricted list because of a legislative mandate which states that, "Approval shall only be given for preparations which are medically justified and which are considered to be needed". Medically justified means that the product must have been shown to be effective and safe: the benefits of treatment must outweigh the risks of adverse effects. Products must also fulfill a therapeutic need which other available products do not. Thus, a product may be safe and effective, but if it has no demonstrable advantages over existing prodcts, it is rejected.

The authority for a decision to register, re-register or withdraw a product rests with the Specialities Board, a five-member Crown-appointed board which includes at least one physician and one pharmacist. The Board has about 8 meetings per year when it reviews summary documents prepared by the drug control staff and makes final decisions. To prepare summaries and a recommendation for a specific product, the drug control staff collects all data and references available from the manufacturer as well as any articles which have been collected or referred to by past consultants. The entire bundle of literature is organized and given to the appropriate specialist consultant to review. It is the review and conclusion of the specialist consultant that forms the basis for the Specialties Board decision. (1978)

Figure II.A.2.

Formulary Revision Form

ALL PERTINENT SECTIONS OF THIS FORM MUST BE COMPLETED. AN INCOMPLETE FORM WILL BE REJECTED.

ADDITION ☐ DELETION ☐

1. Generic Name:

2. Commercial Name(s):

3. Manufacturer(s):

4. Designate the dosage form(s) that you wish to INCLUDE EXCLUDE

TABLET	☐	CAPSULE	☐	AMPULE	☐
SYRUP	☐	ELIXIR	☐	ORAL SOLUTION	☐
OINTMENT	☐	CREAM	☐	SUPPOSITORY	☐

_____ ☐
(Other)

Strength(s):

5. Primary therapeutic indications:

6. Therapeutic class(es):

7. Recommended dosages and duration of therapy: _____ (Pediatric) _____ (Adult)

8. Briefly summarize the therapeutic rationale for the proposed addition or deletion of the drug in relation to its therapeutic category:

9. The drug proposed for addition can replace the following drugs already included in the Formulary:

10. Briefly summarize your clinical experience in the use of the drug (i.e., effects obtained, dosage used, adverse effects, etc.):

11. List the contraindications, precautions, and toxicity associated with the use or abuse of the drug:

12. List a minimum of three journal references of clinical studies which describe the efficacy, toxicity, and/or use of the drug. These references must be from internationally recognized professional journals. References included:

I. _____ (Principal Author) _____ (Journal) (Vol. & Page) _____ (Year)

II. _____ (Principal Author) _____ (Journal) (Vol. & Page) _____ (Year)

III. _____ (Principal Author) _____ (Journal) (Vol. & Page) _____ (Year)

Name (Please Print)

Signature

3. SELECTION CRITERIA: How Should Drugs Be Selected?

Ideally, the selection of drug products should be made only after determining the prevalent diseases being treated within the country, the characteristics of patients being treated, and the level of training of the health personnel who treat these patients. For example, in Central America, parasitic infestations, upper respiratory infections, gastro-intestinal infections, urinary tract infections, injuries, and pregnancies account for most medical care visits. The patients are most often children, pregnant women, and the elderly. Generally, the health personnel treating them are auxiliary health workers. In this setting, attention should be given to selecting the drugs of choice for these diseases, taking into consideration the patients' ages, and the health care workers' abilities.

a. Selection Guidelines

The World Health Organization has carefully considered the process of choosing drugs for public health programs and has suggested detailed selection criteria (Figure II.A.3.). The major principles embodied in these guidelines are the following:

- Select drugs with proven efficacy and acceptable risk determined by studies utilizing accepted scientific methods involving human subjects.
- Select the minimum number of drugs needed to treat the prevalent diseases. Avoid unnecessary duplication and close similarities in drugs or dosage forms.
- Compare newly released products with products having known efficacy and include them only if they are found to have distinct advantages over products currently in use.
- Include combination products only when they provide true benefit over the individual use of each component.
- When several alternatives are available, select drugs with clear "drug of choice" indications for the prevalent diseases in the country.
- Evaluate the administrative and cost impact of products in terms of ease of purchase, storage, distribution, dosage units needed, etc.
- Select drug products for which adequate standards of quality have been established.
- Contraindications, precautions, and adverse effects should be thoroughly investigated and evaluated in order to obtain the benefit/risk ratio of the product.
- Drugs should be referred to by their medical (generic) name when ordered or published on the formulary. With time, increased familiarity with drugs by generic name will decrease physician dependence on trade name recognition and facilitate more economical drug therapy.

Figure II.A.3.

WHO Guidelines for Establishing a List of Essential Drugs

Criteria for the selection of essential drugs are intended to ensure that the process of selection will be unbiased and based on the best available scientific information, yet allow for a degree of variation to take into account local needs and requirements. The following guidelines are recommended :

(1) Each country should appoint a committee to establish a list of essential drugs. The committee should include individuals competent in the fields of clinical medicine, pharmacology and pharmacy, as well as peripheral health workers. Where individuals with adequate training are not available within the country, assistance from WHO could be sought.

(2) Drug selection should be based on the results of benefit and safety evaluations obtained in controlled clinical trials and/or epidemiological studies. Guidelines for such trials have been set forth in the report of a WHO Scientific Group.[1]

(3) The international nonproprietary (generic) names for drugs or pharmaceutical substances should be used whenever available.[2] A cross-index of nonproprietary and proprietary names should initially be provided to the prescribers.

(4) Regulations and facilities should be available to ensure that the quality of selected pharmaceutical products meets adequate quality control standards, including stability and, when necessary, bioavailability. Where national resources are not available for this type of control, the suppliers should provide documentation of the product's compliance with the requested specifications.

(5) Cost represents a major selection criterion. In cost comparisons between drugs, the cost of the total treatment, and not only the unit cost, must be considered. In addition, the cost of nonpharmaceutical therapeutic modalities should be taken into account.

(6) Local health authorities should decide the level of expertise required to prescribe single drugs or a group of drugs in a therapeutic category. Consideration should also be given to the competence of the personnel to make a correct diagnosis. In some instances, while individuals with advanced training are necessary to prescribe initial therapy, individuals with less training could be responsible for maintenance therapy.

(7) The influence of local diseases or conditions on pharmacokinetic and pharmacodynamic parameters should be considered in making the selections : e.g., malnutrition, liver disease.

(8) When several drugs are available for the same indication, select the drug, pharmaceutical product and dosage form that provide the highest benefit/risk ratio.

(9) When two or more drugs are therapeutically equivalent, preference should be given to :

(i) the drug which has been most thoroughly investigated ;

(ii) the drug with the most favourable pharmacokinetic properties, e.g., to improve compliance, to minimize risk in various pathophysiological states ;

(iii) drugs for which local, reliable manufacturing facilities for pharmaceutical products exist ;

(iv) drugs, pharmaceutical products and dosage forms with favourable stability, or for which storage facilities exist.

(10) Fixed-ratio combinations are only acceptable if the following criteria are met :

(i) clinical documentation justifies the concomitant use of more than one drug ;

(ii) the therapeutic effect is greater than the sum of the effect of each ;

(iii) the cost of the combination product is less than the sum of the individual products ;

(iv) compliance is improved ;

(v) sufficient drug ratios are provided to allow dosage adjustments satisfactory for the majority of the population.

(11) The list should be reviewed at least once a year and whenever necessary. New drugs should be introduced only if they offer distinct advantages over drugs previously selected. If new information becomes available on drugs already in the list which clearly shows that they no longer have a favourable benefit/risk ratio, they should be deleted and replaced by a safer drug. It should be remembered that for the treatment of certain conditions, nonpharmacological forms of therapy, or no

Several of these guidelines are discussed in greater detail in the following pages. WHO's own Revised Model List of Essential Drugs is presented in Appendix II.A.3.

b. Drug Nomenclature: What are "Generic Drugs"?

The existence of many names for each drug has led to significant confusion in drug nomenclature. Each drug on the market has a chemical name (e.g., 6-{D(-)-α-Amino-α-phenylacetamido}-penicillanic acid) and a non-proprietary, medical, or generic name (e.g, ampicillin). The generic name is the drug's official name regardless of who manufactures or markets it. A proprietary, commercial, or brand trade name is chosen by the manufacturer or distributor to facilitate recognition and association of the product with a particular firm for marketing purposes (e.g., Polycillin). Regardless of the manufacturer, every drug is a "generic drug". Though it may have a brand name, it will always have a generic equivalent name.

The international nonproprietary names (INN) are assigned through the World Health Organization following a well-established procedure. Proposed and recommnended names are published regularly in the WHO Chronicle and a computerized cumulative compendium of all approved INNs is periodically published by WHO. Official INN listings are in Latin, English, French, Spanish, and Russian. Since national nonproprietary names sometimes differ from the INN, public health programs should specify that the official INN be used whenever the medical (generic) name of a drug is required.

The issue of generic name products carries with it both price and quality considerations. Proponents of "generic" drug purchasing and prescribing point out that drugs sold only by their generic names are frequently less expensive than drugs sold by brand name. Opponents of generic drug purchasing and prescribing argue that the quality of drugs bearing only the generic name is inferior to that of brand name products. Both of these positions deserve attention. In the majority of cases, drugs sold only by generic name have a substantially cheaper wholesale price than the brand name products. Brand name drugs are often 50 to 100 percent more expensive; sometimes the difference is even greater. However, the actual manufacturing costs are comparable so that in competitive tender purchasing, suppliers of brand name drugs can frequently match or, if the brand-name supplier is particularly interested in the business, even underbid the "generic" supplier.

Drug quality and equivalency is a much more complicated issue. Chapter III.D. discusses quality control in detail and reviews the question of drug bioequivalence. It should be clearly understood that the control of drug quality and the naming of drugs are two separate issues. "Generic drugs" from reliable suppliers are as safe and effective as drugs bought by well-known brand names. At the same time, drugs bought by brand name from a local facility whose quality control department has become lax may be of poor quality, despite the brand name. In the United States, drugs sold by generic name have the same low rate of recall that brand name products have.

One reason that drugs may be of equal quality with or without a brand name is that they are often made by the same supplier. For example, a recent survey of U.S. manufacturers showed that ampicillin manufactured by

Bristol Labs is sold to Smith Kline & French (SKF) and Parke-Davis and distributed by all three firms. SKF sells the Bristol-manufactured ampicillin 250 mg. for U.S.$5.76/100, Parke-Davis sells it for $8.91/100, and Bristol sells it for $9.04/100. Thus, the same drug is sold by the maker for nearly twice the price of competitors. Tetracycline is manufactured by Milan Pharmaceuticals and distributed by A.H. Robins as Robitet for $3.25/100, by SKF as SK-Tetracycline for $2.30/100, and by Interstate Drug Exchange as Tetracycline for $2.50/100. Sometimes a well-known multinational drug company which deals exclusively in brand name products will have a subsidiary firm which manufactures drugs using the same raw materials and process, but sells them only by generic name.

In summary, drug nomemclature has an important impact on price: drugs bought by brand name are often more expensive and sometimes by a large margin. But this is not always the case; procurement officers should not assume that brand name drugs will be more costly. The relationship between drug nomenclature and quality is more complex. Brand name alone should not be used to judge quality. A system of quality control (Chapter III.D.) should be part of any procurement program.

c. Multiple Dosage Forms

Most drugs are available in different dosage forms. For example, tetracycline comes in capsules, suspension, and ampules. For procurement purposes, each dosage form represents an additional item on the list and, consequently, additional administrative and inventory expenses. Nonessential dosage forms should thus be avoided. Furthermore, different dosage forms may have different prices. Piperazine oral suspension, for example, costs much more than tablets, yet both forms are needed -- the syrup for infants and the tablets for children and adults. In such cases, a public program should buy only the amount of the more expensive dosage form that is required. Using expensive dosage forms where cheaper ones will do wastes limited funds.

d. Local Remedies

Physicians and health care workers serving remote regions of developing countries often turn to herbal or naturalist remedies that have been known and used over the ages. Although many of these have no therapeutic justification, others do, and to totally eliminate them may not be in the best interest of the health care system, either medically or economically. Some examples of local remedies are passiflora (an antispasmodic sedative) and lignin (an antidiarrheal). A formulary committee could establish a brief period during which local medicinal remedies could be proposed for inclusion into the formulary. This "grandfathering" period -- which might last 60 days -- would occur only during the initial formulary development, and would permit the inclusion of drugs not meeting the strict admissability criteria previously outlined. "Local remedies" may thus be selectively admitted to the formulary. By making such a procedure available, not only is acceptance of the formulary enhanced, but some low-cost, locally produced, therapeutically-acceptable alternatives may be added.

Figure II.A.4.

Therapeutic Categories for a National Drug List

1. Anaesthetics
2. Analgesics, Antipyretics, Nonsteroidal Antiinflammatory Drugs and Drugs Used to Treat Gout
3. Analgesics, Narcotics, and Narcotic Antagonists
4. Antiallergics (Antihistamines)
5. Antidotes
6. Antiepileptics
7. Antiinfective Drugs
   - 7.1. Amoebicides
   - 7.2. Antihelminthic drugs
   - 7.3. Antibacterial drugs
   - 7.4. Antifilarial drugs
   - 7.5. Antileprosy drugs
   - 7.6. Antimalarials
   - 7.7. Antischistosomals
   - 7.8. Antitrypanosomals
   - 7.9. Antituberculosis drugs
   - 7.10. Leishmaniacides
   - 7.11. Systemic antifungal drugs
8. Antimigraine drugs
9. Antineoplastic and Immunosuppressive Drugs
10. Antiparkinsonism Drugs
11. Blood, Drugs Affecting the
    - 11.1. Antianaemia drugs
    - 11.2. Anticoagulants and antagonists
12. Blood Products and Blood Substitutes
13. Cardiovascular Drugs
    - 13.1. Antianginal drugs
    - 13.2. Antiarrhythmic drugs
    - 13.3. Antihypertensive drugs
    - 13.4. Cardiac glycosides
    - 13.5. Drugs used to treat shock or anaphylaxis
14. Dermatological Drugs
15. Diagnostic Agents
16. Diuretics
17. Gastrointestinal Drugs
    - 17.1. Antacids
    - 17.2. Antiemetics
    - 17.3. Antihemorrhoidals
    - 17.4. Antispasmodics
    - 17.5. Cathartics
    - 17.6. Diarrhea
      - 17.6.1. Antidiarrheal
      - 17.6.2. Replacement solution
18. Hormones
    - 18.1. Adrenal hormones and synthetic substitutes
    - 18.2. Androgens
    - 18.3. Estrogens
    - 18.4. Insulins
    - 18.5. Oral contraceptives
    - 18.6. Progesterones
    - 18.7. Thyroid hormones and antagonists
    - 18.8. Ovulation inducers
19. Immunologicals
    - 19.1. Sera and immunoglobulins
    - 19.2. Vaccines
20. Muscle Relaxants (peripherally acting and Cholinesterase Inhibitors)
21. Ophthalmological Preparations
22. Oxytocics
23. Peritoneal Dialysis Solution
24. Psychotherapeutic Drugs
25. Respiratory Tract, Drugs Acting on the
    - 25.1. Antiasthmatic drugs
    - 25.2. Antitussives
26. Solutions Correcting Water, Electrolyte, and Acid-Base Disturbances
    - 26.1. Oral
    - 26.2. Parenteral
27. Surgical Disinfectants
28. Vitamins and Minerals

Abstracted from WHO Technical Report Series, No. 641, "The Selection of Essential Drugs", 1979.

e. Formulary Structure

The essential list of drugs can be structured in several ways: by therapeutic/pharmacologic class, by indication, by alphabetic order, or by level-of-use. Most essential drug lists are structured primarily by therapeutic/pharmacologic class (see WHO's Therapeutic Categories for a National Drug List, Figure II.A.4.) with additional listings by level-of-use (discussed below). Within these therapeutic classes, the drugs are listed generically, by alphabetic order, or by importance or frequency of use. An example of a drug list structured by therapeutic category and level-of-use is presented in Appendix II.A.2.

Several countries have developed a "therapeutic" formulary. This "therapeutic" designation is assigned because of the inclusion of prescribing information as part of the formulary itself in a ready reference format. Structured by therapeutic class, this formulary provides general prescribing information regarding drug class and usage instructions for the patient. Each product is listed generically, and includes the product's strength and dosage form. A level-of-use is also designated for each product. Drugs of choice are highlighted by an asterisk to facilitate their easy recognition. Average dosage regimens (pediatric and adult) and recommended duration of treatment are presented. Finally, the "therapeutic" formulary contains contraindications precautions, adverse effects, drug interactions, and other relevant prescribing observations for each product. Chapter V.A. provides several examples of such listings.

f. Level-of-Use

Proper prescribing of a drug is dependent on a proper diagnosis and adequa knowledge of the drug. For example, diagnosing and treating an acute episode o headache with aspirin requires only minimal training. But extensive training is necessary to be able to diagnose a cancer and to monitor the use of a potent anti-cancer drug. Therefore, the level of training of the health personnel and the types of conditions treated at any given health care delivery level must be considered when determining which drugs should be stocked at each level. Potent drugs for the treatment of diseases requiring sophisticated diagnostic procedures should be stocked only at the tertiary care level where they will be used only by trained specialists. Simple remedies used for acute symptomatic treatment (such as aspirin, antihistamines, laxatives, etc.) should be stocked from the primary care level on up. Many formularies use a four-level system based on type of facility, the training of the medical practitioner, or both. A typical division might be:

Level-of-Use	Examples of Drugs	Medical Practitioner	Facility
1	Aspirin, Antacids, Antihistamines	Village Health worker All Higher Levels	Village, Aid Post All Higher Levels
2	Insulin, Anti-hypertensives, Antibiotics	Medical Auxiliary General Practitioner All Higher Levels	Health Center All Higher Levels

3	Anesthetics, Injectable Diuretics, Antibiotics	Hospital Specialist All Higher Levels	District Hospital All Higher Levels
4	Anticancer Agents	Specialist	Specialist Hospitals National Hospital

Country Study II.A.2. describes the level-of-use prescribing practices that are followed in several countries.

Country Study II.A.2.

Level-of-Use Prescribing in Selected Countries

Costa Rica -- Health Centers and Health Posts are limited to less than 130 drugs for use in preventive and basic curative medicine. The Cuadro Basico de Medicamentos (Basic Chart of Medicines) for the Social Security Fund which operates most of the country's hospitals divides drugs into those for general use, for pediatric use, and for hospital use only. Among those for general use, a large number are reserved for use by specialists only. (1978)

Papua New Guinea -- Items in the Medical Stores Catalogue are divided according to the qualifications of the health workers allowed to order each item. No one can order a drug marked for health workers with a higher medical qualification without formal approval. The categories are: (A) medical officers, medical assistants and nurses, (IW) staff providing approved maternal and child health services, (B) medical officers, (C) specialist medical officers only, (D) medical officers needing restricted items, and (E) pharmacists only (raw materials). There is some flexibility in this listing. For example, if a medical officer discharges a patient to the care of a nurse and the patient requires a category B drug, the medical officer can make supplies of the drug available to the nurse. Also, in some situations, general medical officers will be allowed to use category C drugs. (1978)

Honduras -- The national formulary is divided into levels of care, with the main divisions being national hospitals, regional hospitals, local hospitals, health centers, and health posts. The level of care division is used to direct drug distribution. It is also intended to be used in conjunction with morbidity data and treatment norms to estimate expected drug consumption. (1977)

Sri Lanka -- The Standard List of Drugs for government medical institutions contains separate drug lists for each of the following types of institutions: (1) general hospitals; (2) base hospitals; (3) district hospitals; (4) rural hospitals and peripheral units staffed by a medical auxiliary; (6) central dispensaries; and (7) maternity clinics staffed by midwives. Although the original list is now outdated and a new complete list is pending, the basic distinctions remain. The regional superintendents of health services, who are responsible for the drug budget for all inpatient and outpatient services within their region, have some flexibility in determining which facilities will receive which types of drugs. (1978)

Czechoslovakia -- Antibiotics have been divided into three categories: those which may be prescribed without limitation by all physicians; those which may be prescribed by hospital physicians only on special order forms, and those which may be prescribed only on the recommendation of an infectious disease specialist. The result of this policy has been a leveling of the trend toward antbiotic resistance and a decrease in antibiotic-related side effects. Restrictions also exist for the use of several drug categories by qualified specialists only. These drug categories include chemotherapeutic agents for neoplasms, tuberculosis drugs, and certain psychotropic drugs. (1977)

Canada and the United States -- Local hospital pharmacy and therapeutics committees impose restrictions on the prescribing of certain items. Certain antibiotics--for example gentamicin or tobramycin--may be restricted to use by infectious disease specialists only. New drugs such as chemotherapeutic agents may be restricted to use by a specified consultant group only. (1980)

g. Information Resources

Sources of information for drug selection decisions are frequently limited in availability in most developing countries. Of the many valuable resources that could be consulted, the following four sources are most useful: Martindale: The Extra Pharmacopeia, recent issues of The Medical Letter, The Pharmacologic Basis of Therapeutics, and the the W.H.O. Selection of Essential Drugs. Drug selection decisions can be made with relative confidence when utilizing these sources. Appendix II.A.1. provides a more complete listing of potential sources of information, some of which will be provided on request without charge to public health officials.

For newly released drugs, it is frequently difficult to obtain sufficient information on efficacy, toxicity, recommended dosages, etc. Often, objective evaluations of new drugs are not available until sufficient experience with the drug has accumulated. Hence, a rational approach to drug selection would be to delay including a newly released drug until sufficient information is available through respected published sources.

4. GAINING ACCEPTANCE OF AN ESSENTIAL DRUG LIST

There are several techniques that can be used for gaining acceptance of an essential drug list by Ministry of Health personnel, health care providers, and patients. An important first step is to obtain the support of the organized physician community (e.g., the national medical association) by consulting them early on and discussing with them the rationale for developing a basic drug list and the criteria to be employed in selecting drugs for inclusion. In several countries, this approach has resulted in obtaining written endorsement of the essential drug list from the medical association.

Acceptance by physicians and other health care workers is enhanced by including objective drug information such as indications, recommended dosages for children and adults, duration of treatment, contraindications, precautions, adverse effects, and administration and storage suggestions. Objective drug information is of limited availability in most developing countries, and health care workers must be alerted to possible misleading labeling and promotional literature claims.

Experience has shown that the provision of such objective drug information is considered worthwhile by physicians and other health care workers throughout developing countries. Thus, although the number of pharmaceutical products for public health use is reduced by an essential drug list, the practical availability of complete and objective drug information on these products offsets professional resistance. Moreover, the Ministry of Health's image benefits from its public position in favor of informed drug prescribing and use. Chapter V.A. provides some details regarding methods of providing drug information to practitioners.

Another useful technique which enhances acceptance of the basic drug list is a public interest advertising campaign directed toward the general population. Such a campaign should stress that the government's limited resources are being judiciously spent on carefully selected, efficacious, safe drugs which are essential for treatment of the country's prevalent diseases. Additionally, it should be emphasized that the use of an essential drug list will ensure that needed products are available at the local level. Further discussion of public interest campaigns appears in Chapter V.C.

SUMMARY

Limited drug funds are frequently spent on ineffective, duplicative, or unacceptably dangerous drugs.

Development of a standard drug list or program formulary offers two major benefits:

(1) Therapeutic gain through improved drug information and utilization.
(2) Economic and Administrative gain through more efficient procurement and distribution.

Drug selection can be done by individual procurement officers, by a selection committee, or by an independent pharmacology consultant. The committee approach offers numerous advantages and is probably preferable in most instances.

Selection may occur at the national level or at regional or local levels. Establishment of a single national drug list offers the greatest potential economic and administrative gains, but regional or local drug selection allows for local preferences and may achieve greater acceptance.

WHO has prepared guidelines for establishing a drug list for public health programs. The major principles are:

- Selections should be supported by scientific proof of effectiveness and safety.
- Duplication should be avoided.
- Combination drugs should be used only if they offer a needed benefit over single entity drugs.
- Cost is a major selection factor; when choosing among clinically comparable drugs, the least expensive is nearly always preferred.
- Local diseases, patient characteristics, and health care worker training should be considered.
- Drugs should be referred to by their medical (generic or INN) names only.

Some local remedies are effective and are worthy of consideration for the formulary.

The formulary should be organized into categories by:

(1) therapeutic class,
(2) indication or disease category, and/or
(3) level-of-use.

In order for it to have the intended impact, an essential drug list or program formulary must gain the acceptance of Ministry of Health officials, physicians and other medical practitioners, and patients. Several techniques are described for achieving acceptance of the formulary.

Appendix II.A.1.

Information Sources of Value in Drug Selection

a. General

Collins, G.E. and Lazarus, H.L.: Drug Information Services Handbook. Acton, MA: Publishing Service Group, 1975.

Drug Information Sources: A Worldwide Annotated Survey. Henley-on-Thames, Oxon, England: Gothard House Publications, Ltd., 1978.

Sewell, W.: Guide to Drug Information. Hamilton, Illinois: Drug Intelligence Publications, Inc., 1976.

Silverman, M.: The Drugging of the Americas. Berkeley: University of California Press, 1976, 147 pp. $8.50

Speight, A.M.P.: Cost-Effectiveness and Drug Therapy. Tropical Doctor: 89-92, April, 1975.

World Health Organization: Nonproprietary Names for Pharmaceutical Substances. Twentieth Report of the WHO Expert Committee. Geneva: World Health Organization, Technical Report Series No. 581, 1975.

World Health Organization: The Promotion and Development of Traditional Medicine. Geneva: World Health Organization, Technical Report Series No. 622, 1978.

World Health Organization: The Selection of Essential Drugs. Geneva: World Health Organization, Technical Report Series No. 615, 1977, and No. 641, 1979.

b. Reference Books

American Pharmaceutical Association: Handbook of Nonprescription Drugs, 5th Edition. Washington, D.C.: American Pharmaceutical Association, 1977, 388 pp.

Bochner, F., Carruthers, G., Kampmann, J., Steiner, J., and Azarnoff, D.L.: Handbook of Clinical Pharmacology. Boston, MA: Little, Brown & Co., 1978.

Goodman, L. S. and Gilman, A.: The Pharmacological Basis of Therapeutics, 4th edition. New York: The MacMillan Company, 1970, 1794 pp. $30.00.

Kastrup, E.K.: Facts and Comparisons. St. Louis: Facts and Comparisons, Inc., 1980.

Knoben, J.E. et al.: Handbook of Clinical Drug Data, 4th Edition. Hamilton, Illinois: Drug Intelligence Publications, 1978, 467 pp., $15.00.

United States Pharmacopeia Dispensing Information, Easton, Pennsylvania: Mack Publishing Company, 1980, 792 pp.

Wade A. (ed): Martindale: The Extra Pharmacopoeia, 27th Edition. London: The Pharmaceutical Press, 1977, 2077 pp., $60.00.

c. Periodicals

Drug Information
Dr. J. F. Dunne, Senior Medical Officer, Pharmaceuticals Unit,
Division of Prophylactic, Diagnostic, and Therapeutic Substances
World Health Organization
1211 Geneva 27
Switzerland

Drugs of the Future
J. R. Prous, Editor
Apartado de Correos 1641
Barcelona, Spain

Drugs of Today (Medicamentos de Actualidad)
J. R. Prous, Editor
Apartado de Correos 1641
Barcelona, Spain

Drugs and Therapeutic Bulletin
Consumers' Association
14 Buckingham Street
London W.C.2, England

CLIN-ALERT
Science Editors, Inc.
149 Thierman Lane
P. O. Box 7185
Louisville, KY, USA

International Pharmaceutical Abstracts
4630 Montgomery Avenue
Washington, D.C. 20014, USA

The Medical Letter (on Drugs and Therapeutics)
The Medical Letter, Inc.
56 Harrison Street
New Rochelle, NY 10801, USA
(Available in English, French, Spanish, and Italian)

Prescribers' Journal
Hannibal House
Elephant and Castle
London SE1 6TE, England

d. National Drug Control Agency Publications

Australian Prescriber -- published quarterly; available in English; no charge. Drug Profiles -- available in English; no charge.
Australian Department of Health
P.O. Box 100
Woden, A.C.T. 2606, AUSTRALIA

Austria-Codex -- published annually; available in German.
Bundesministerium für Gesundheit
und Umweltschutz
(Federal Ministry of Health and
Environmental Protection)
Osterreichischen ApothekerverlagsgesmbH
Spital-Gasse 31
A - 1090 Vienna, AUSTRIA

The National Formulary; Index of Specialties -- published periodically; available on a limited scale in English.
General Administration of Pharmacy
Ministry of Public Health
Cairo, EGYPT

Drugs Information Sheet -- published periodically. Reports of Side Effects Associated with the Use of Drugs -- published yearly; cummulative since 1968.
National Drugs Advisory Board
Charles Lucas House
57C Harcourt Street
Dublin 2, IRELAND

Medical Newsletter Alon maidah Trufate -- available in English and Hebrew.
Pharmaceutical Division
Ministry of Health
8 a, Hurkania Street
Jerusalem, ISRAEL

Prescribers' Notes -- available in English; no charge.
Division of Clinical Services
Department of Health
P.O. Box 5013
Wellington, NEW ZEALAND

FDA Drug Bulletin -- available in English; no charge.
Department of Health, Education and Welfare
Public Health Service
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20852, U.S.A.

e. Pharmaceutical Industry Publications

The following is a partial listing of pharmaceutical industry compendia which may be of value in locating potential suppliers for specific products and in identifying the generic contents of brand name products. Although most of these publications contain Indications, Side Effects, Warnings, Dosage, etc., the reader should be aware that these publications often are not reviewed by an unbiased source and that indications are frequently overstated and adverse effects understated. Many of these publications are free.

Compendium of Pharmaceuticals and Specialties (CPS)
Canadian Pharmaceutical Association
175, College Street
Toronto, Canada

Diccionario De Especialidades Farmaceuticas
Landero and Rosenstein
Mexico City, Mexico
(Covers the drugs of Costa Rica, El Salvadore, Guatemala, Honduras, Nicaragua, Panama, Dominican Republic)

Dictionnaire Vidal
O.V.P., 11 Rue Quentin-Bauchart
75008 Paris, France

DIE LISTE Pharmindex I/75
I.M.P. Verlagsgesellschaft mbH,
Neu Isenburg, Beethovenstrasse 2,
6078 Neu Isenburg, Federal Republic of Germany

Indian Pharmaceutical Guide
Mohan C. Bazaz, Prem Nath Bazaz,
Kanwal Kishore, Pamposh Publications
E-38, Hauz Khas
New Delhi 110 016, India

L'Informatore Farmaceutico
(Italian Directory of Drugs and Manufacturers)
Dr. Lucio Marini, Organizzazione Editoriale
Medico-Farmaceutica S.R.L.
Via Edolo 42
20125 Milano, Italy

MIMS (Monthly Index of Medical Specialties)
Haymarket Publishing Ltd., Medical Division
Regent House, 54/62 Regent Street
London W1A 4YJ, England

African MIMS
P. O. B. 150
St. Helier, Jersey
Channel Islands
(Circulated in Ethopia, Gambia, Ghana, Kenya, Liberia, Malawi, Nigeria, Rhodesia, Sierra Leone, Sudan, Tanzania, Uganda, Zambia)

MIMS Caribbean
P. O. Box 150
St. Helier, Jersey
Channel Islands
(Circulated in Bahamas, Bermuda, Bratish Honduras, Curacao, Guyana, Jamaica, Surinam, Trinidad)

MIMS Far East
Medical Mailing International
P.O.B. 150
St. Helier, Jersey
Channel Islands
(Circulated in Indonesia, Malaysia, Brunei, Singapore, Thailand, Hong Kong)

MIMS Japan
Scientific Publications Division
IMS, Tokyo, Japan

MIMS Middle East
Medical Mailing International
P.O.B. 150
St. Helier, Jersey
Channel Islands
(Circulated in Bahrain, Cyprus, Iran, Iraq, Jordan, Kuwait, Lebanon, Libya, Qatar, Saudi Arabia)

Pharmazeutisch Stoffliste
Arzneibüro der ABDA
Beethovenplatz 1-3
6 Frankfurt (Main), Federal Republic of Germany

Physicians' Desk Reference (PDR)
Charles E. Baker, Jr.,
Medical Economics Company
Oradell, N.J. 07649, U.S.A.

Repertorium Verpakte Geneesmiddelen
Uitgeverij de Toorts
Haarlem, The Netherlands

Appendix II.A.2.

Example of a Drug List Structured by Therapeutic Category and Level-of-Use

THERAPEUTIC CATEGORY Name of Drug	LEVEL-OF-USE Community Health Workers	Dispensaries	Health Centers	Hospitals
A. ANESTHETICS				
Anesthetic ether			x	x
Halothane			x	x
Sodium pentothal			x	x
Lidocaine		x	x	x
B. ANALGESICS				
Aspirin	x	x	x	x
Codeine			x	x
C. GASTROINTESTINAL PREPARATIONS				
Hyoscyamine sulfate		x	x	x
Magnesium trisilicate		x	x	x
Mineral oil			x	x
D. ANTI-ALLERGICS				
Diphenhydramine		x	x	x
E. SEDATIVES				
Diazepam (injectable)			x	x
Phenobarbital		x	x	x
F. ANTI-PARASITICS				
Metronidazole			x	x
Mebendazole			x	x
Piperazine	x	x	x	x
G. ANTI-TUBERCULARS				
Isoniazid			x	x
H. ANTI-MALARIALS				
Chloroquine phosphate (capsules)	x	x	x	x
Chloroquine phosphate (injectable)			x	x
I. ANTIBIOTICS				
Penicillin (tablets and suspension)		x	x	x
Penicillin (procaine and benzathine)			x	x
Triple sulfa tablets		x	x	x
Chloramphenicol (tablets and suspension)			x	x
Tetracycline syrup			x	x

J. VITAMINS AND MINERALS				
Multivitamins with folate and iron (capsules and liquid)	x	x	x	x
Ferrous sulfate (capsules and liquid)	x	x	x	x
Vitamin A	x	x	x	x
Vitamin K			x	x
K. RESPIRATORY SYSTEM MEDICATIONS				
Phenylephrine		x	x	x
Epinephrine			x	x
Aminophylline		x	x	x
L. OPHTHALMIC PREPARATIONS				
Silver nitrate		x	x	x
Sulfacetamide solution	x	x	x	x
Tetracycline ointment		x	x	x
M. DERMATOLOGICAL PREPARATIONS				
Gentian violet	x	x	x	x
Benzyl benzoate		x	x	x
Calamine lotion	x	x	x	x
N. CARDIAC AND ANTI-HYPERTENSIVE MEDICATIONS				
Epinephrine			x	x
Digitoxin			x	x
Reserpine		x	x	x
Chlorthiazide			x	x
O. HORMONES				
Insulin (regular)			x	x
Cortisone (injectable)			x	x
P OXYTOCICS				
Ergometrine maleate			x	x
Q. BLOOD SUBSTITUTES				
Dextran			x	x
R. ELECTROLYTE SOLUTIONS				
Oral rehydration packets	x	x	x	x
5 % Dextrose			x	x
Lactated ringers			x	x
Normal saline			x	x
S. VACCINES AND IMMUNOLOGICALS				
Antitetanus serum			x	x
DPT		x	x	x
Tetanus		x	x	x
Polio		x	x	x
Rubeola		x	x	x
T. CONTRACEPTIVES				
Oral contraceptive tablets		x	x	x

Appendix II.A.3.

WHO Revised Model List of Essential Drugs

Explanatory Notes*

I. Numbers in parentheses following the drug names indicate:

(1) Listed as an example of this therapeutic category: choose cheapest effective drug product acceptable;
(2) Specific expertise, diagnostic precision or special equipment required for proper use;
(3) Greater potency;
(4) In renal insufficiency, contraindicated or dosage adjustments necessary;
(5) To improve compliance;
(6) Special pharmacokinetic properties for purpose;
(7) Adverse effects diminish benefit/risk ratio;
(8) Limited indications or narrow spectrum of activity;
(9) For epidural anaesthesia;
(10) Drugs subject to international control under the Single Convention on Narcotic Drugs (1961) and the Convention on Psychotropic Substances (1971).

II. Letters in parentheses following the drug names indicate the reasons for the inclusion of *complementary drugs*:

(A) When drugs in the main list cannot be made available;
(B) When drugs in the main list are known to be ineffective or inappropriate for a given individual;
(C) For use in rare disorders or in exceptional circumstances.

* The numbers preceding the drug groups and subgroups in the model list (e.g., 11; 17.6.2) have been allocated, in accordance with the English alphabetical order, for convenience in referring to the various categories; they have no formal significance — Ed.

Main list	*Complementary drugs*	*Route of administration, pharmaceutical forms and strengths*[a]
1. Anaesthetics		
1.1 General anaesthetics and oxygen		
ether, anaesthetic (2)		inhalation
halothane (2)		inhalation
nitrous oxide (2)		inhalation
oxygen		inhalation (medicinal gas)
thiopental (2)		powder for injection, 0.5 g, 1.0 g (sodium salt) in ampoule
1.2 Local anaesthetics		
bupivacaine (1, 2, 9)		injection, 0.25%, 0.5% (hydrochloride) in vial
lidocaine (1)		injection, 1%, 2% (hydrochloride) in vial
		injection, 1%, 2% + epinephrine 1:100 000 in vial
		topical forms, 2–4% (hydrochloride)
2. Analgesics, Antipyretics, Nonsteroidal Antiinflammatory Drugs and Drugs Used to Treat Gout		
acetylsalicylic acid		tablet, 100–500 mg
		suppository, 50–150 mg
allopurinol (4)		tablet, 100 mg
ibuprofen (1)		tablet, 200 mg
indometacin		capsule or tablet, 25 mg
paracetamol		tablet, 100–500 mg
		suppository, 100 mg
	colchicine (B, C) (7)	tablet, 0.5 mg
	probenecid (B, C)	tablet, 500 mg
3. Analgesics, Narcotics and Narcotic Antagonists		
morphine (10)		injection, 10 mg (sulfate or hydrochloride) in 1 ml ampoule
naloxone		injection, 0.4 mg (hydrochloride) in 1 ml ampoule
	pethidine (A) (1, 4, 10)	injection, 50 mg (hydrochloride) in 1 ml ampoule
4. Antiallergics		
Antihistamines		
chlorphenamine (1)		tablet, 4 mg (maleate)
5. Antidotes		
5.1 General		
charcoal, activated		powder
ipecacuanha		syrup, containing 0.14% ipecacuanha alkaloids calculated as emetine
5.2 Specific		
atropine		injection, 1 mg (sulfate) in 1 ml ampoule
deferoxamine		injection, 500 mg (mesilate) in vial
dimercaprol (2)		injection in oil, 50 mg/ml in 2 ml ampoule
sodium calcium edetate (2)		injection, 200 mg/ml in 5-ml ampoule
sodium nitrite		injection, 30 mg/ml in 10 ml ampoule
sodium thiosulfate		injection, 250 mg/ml in 50 ml ampoule
	methylthioninium chloride (C)[b]	injection, 10 mg/ml in 10-ml ampoule
	penicillamine (C) (2)	capsule or tablet, 250 mg
6. Antiepileptics		
diazepam		injection, 5 mg/ml in 2-ml ampoule
ethosuximide		capsule or tablet, 250 mg
phenobarbital (10)		tablet, 50 mg, 100 mg
		syrup, 15 mg/5 ml
phenytoin		capsule or tablet, 25 mg, 100 mg (sodium salt)
		injection, 50 mg (sodium salt)/ml in 5 ml vial
	carbamazepine (B, C)	tablet, 200 mg
	valproic acid (B, C) (2, 4, 7)	tablet, 200 mg (sodium salt)
7. Antiinfective Drugs		
7.1 Amoebicides		
metronidazole		tablet, 200–500 mg
	diloxanide (A)	tablet, 500 mg (furoate)
	emetine (A, B) (1, 7)	injection, 60 mg (hydrochloride) in 1 ml ampoule
	paromomycin (B)	capsule, 250 mg (as sulfate)
		syrup, 125 mg (as sulfate)/5 ml
7.2 Anthelmintic drugs		
mebendazole		tablet, 100 mg
niclosamide		tablet, 500 mg
piperazine		tablet, 500 mg (citrate or adipate)
		elixir or syrup (as citrate) equivalent to 500 mg hydrate/5 ml
thiabendazole		chewable tablet, 500 mg
	bephenium hydroxynaphthoate (B) (8)	granules, 5 g (equivalent to 2.5 g bephenium)

[a] When the strength is specified in terms of a selected salt or ester, this is mentioned in brackets; when it refers to the active moiety, the name of the salt or ester in brackets is preceded by the word "as".

[b] Synonym: methylene blue.

Main list	Complementary drugs	Route of administration, pharmaceutical forms and strengths[a]
7. Antiinfective Drugs *(continued)*		
7.1 Antibacterial drugs		
...pcillin (1,4)		capsule or tablet, 250 mg, 500 mg (anhydrous)
		powder for oral suspension, 125 mg (anhydrous)/5 ml
		powder for injection, 500 mg (as sodium salt) in vial
...nzathine benzylpeni...cillin (5)		injection, 1.44 g benzylpenicillin (= 2.4 million IU)/5 ml in vial
...nzylpenicillin		powder for injection, 0.6 g (= 1 million IU), 3.0 g (= 5 million IU) (as sodium or potassium salt) in vial
...loramphenicol (7)		capsule, 250 mg
		powder for injection, 1 g (as sodium succinate) in vial
...xacillin (1)		capsule, 500 mg (as sodium salt)
		powder for injection, 500 mg (as sodium salt) in vial
...rythromycin		capsule or tablet, 250 mg (as stearate or ethylsuccinate)
		oral suspension, 125 mg (as stearate or ethylsuccinate)/5 ml
		powder for injection, 500 mg (as lactobionate) in vial
...ntamicin (4)		injection, 10 mg, 40 mg (as sulfate)/ml in 2 ml vial
...etronidazole		tablet, 200–500 mg
...enoxymethylpenicillin		tablet, 250 mg (as potassium salt)
		powder for oral suspension, 250 mg (as potassium salt)/5 ml
...lazosulfapyridine (3)		tablet, 500 mg
...ll idinone (1, 4)		tablet, 500 mg
		oral suspension, 500 mg/5 ml
		injection, 1 g (sodium salt) in 3-ml ampoule
...ll amethoxazole + trimethoprim (4)		tablet, 100 mg + 20 mg, 400 mg + 80 mg
...tracycline (1, 4)		capsule or tablet, 250 mg (hydrochloride)
	amikacin (B, C) (1, 4)	injection, 250 mg (sulfate)/ml in 2 ml ampoule
	doxycycline (B) (5, 6)	capsule or tablet, 100 mg (as hydrochloride) injection, 100 mg (as hydrochloride)
	nitrofurantoin (A, B) (4, 7)	tablet, 100 mg
	procaine benzyl penicillin (A) (7)	powder for injection, 1 g (= 1 million IU), 3 g (= 3 million IU)
7.4 Antifilarial drugs		
...ethylcarbamazine		tablet, 50 mg (citrate)
...ronin sodium		injection, 1 g in vial
7.5 Antileprosy drugs		
...psone		tablet, 100 mg
	clofazimine (B)	capsule, 100 mg
	rifampicin (B)	capsule or tablet, 150 mg, 300 mg
7.6 Antimalarials		
...loroquine (1)		tablet, 150 mg (as phosphate or sulfate)
		syrup, 50 mg (as phosphate or sulfate)/5 ml
...modiaquine		tablet, 7.5 mg, 15 mg (as phosphate)
...proguanil		tablet, 25 mg
...mine		tablet, 300 mg (as bisulfate or sulfate) injection, 300 mg (as dihydrochloride)/ml in 2 ml ampoule or 250 mg (as formate) in 1 ml ampoule
	sulfadoxine + pyrimethamine (B)	tablet, 500 mg + 25 mg
7.7 Antischistosomals		
...triconate		tablet, 100 mg
...riquel azole (7, 8)		tablet, 100 mg, 500 mg
...niquine		capsule, 250 mg
		syrup, 250 mg/5 ml
	antimony calcium tartrate (B)	injection, 60 mg in 1 ml ampoule
	sodium stibogluconate	injection, 500 mg

Main list	Complementary drugs	Route of administration, pharmaceutical forms and strengths[a]
7. Antiinfective Drugs *(continued)*		
7.8 Antitrypanosomals		
melarsoprol (5)		injection, 3.6% solution
nifurtimox		tablet, 30 mg, 120 mg, 250 mg
pentamidine (5)		powder for injection, 300 mg (isetionate or mesilate)
suramin sodium		powder for injection, 1 g in vial
7.9 Antituberculosis drugs		
ethambutol		tablet, 100–500 mg (hydrochloride)[c]
isoniazid		tablet, 100 mg–300 mg
rifampicin		capsule or tablet, 150 mg, 300 mg
streptomycin (4)		injection, 1 g (as sulfate)
7.10 Leishmaniacides		
pentamidine (5)		powder for injection, 200 mg (isetionate or mesilate)
sodium stibogluconate		injection, 33%, equivalent to 10% antimony, in 30-ml vial
7.11 Systemic antifungal drugs		
amphotericin B		injection, 50 mg in vial
griseofulvin (8)		tablet or capsule, 125 mg, 250 mg
nystatin		tablet, 500 000 IU
	flucytosine (B) (1, 4, 8)	tablet or capsule, 250 mg
8. Antimigraine Drugs		
ergotamine (2, 7)		tablet, 2 mg (as tartrate)
9. Antineoplastic and Immunosuppressive Drugs		
azathioprine (2)		tablet, 50 mg
		powder for injection, 100 mg (as sodium salt) in vial
bleomycin (2)		powder for injection, 15 mg (as sulfate) in vial
busulfan (2)		tablet, 2 mg
calcium folinate (2)[d]		tablet, 15 mg
		injection, 3 mg/ml in 10-ml ampoule
chlorambucil (2)		tablet, 2 mg
cyclophosphamide (2)		tablet, 25 mg[e]
		powder for injection, 500 mg in vial
cytarabine (2)		powder for injection, 100 mg in vial
doxorubicin (1, 2)		powder for injection, 10 mg, 50 mg (hydrochloride) in vial
fluorouracil (2)		injection, 50 mg/ml in 5-ml ampoule
methotrexate (2)		tablet, 2.5 mg (as sodium salt)
		injection, 50 mg (as sodium salt) in vial
procarbazine (2)		capsule, 50 mg (as hydrochloride)
vincristine (2)		powder for injection, 1 mg, 5 mg (sulfate) in vial
10. Antiparkinsonism Drugs		
levodopa		tablet or capsule, 250 mg
trihexyphenidyl (1)		tablet, 2 mg, 5 mg (hydrochloride)
	levodopa + carbidopa (B) (1, 5, 6)	tablet, 100 mg + 10 mg, 250 mg + 25 mg
11. Blood, Drugs Affecting the		
11.1 Antianaemia drugs		
ferrous salt (1)		tablet, equivalent to 60 mg iron (as sulfate or fumarate)
folic acid (2)		tablet, 1 mg
		injection, 1 mg in 1 ml ampoule
	iron dextran (B) (1, 5)	injection, equivalent to 50 mg iron/ml in 2-ml ampoule
hydroxocobalamin (1, 2)		injection, 1 mg in 1 ml ampoule
11.2 Anticoagulants and antagonists		
heparin (2)		injection, 1000 IU/ml, 25 000 IU/ml in 5 ml ampoule

[redacted]

Main list	Complementary drugs	Route of administration, pharmaceutical forms and strengths[a]
11. Blood, Drugs Affecting the *(continued)*		
11.2 *Anticoagulants and antagonists* (continued)		
phytomenadione		injection, 10 mg/ml in 5 ml ampoule
protamine sulfate (2)		injection, 10 mg/ml in 5 ml ampoule
warfarin (1, 2, 6)		tablet, 5 mg (sodium salt)
12. Blood Products and Blood Substitutes		
12.1 *Plasma substitute*		
dextran 70		injectable solution, 6%[a]
12.2 *Plasma fractions for specific uses*		
albumin, human normal (2, 8)		injectable solution, 25%[a]
	antihaemophilic fraction[a] (C) (2, 8)	(dried)
	fibrinogen (C) (2, 8)	(dried)
	plasma protein (C) (2, 8)	injectable solution, 5%[a]
	factor IX complex (coagulation factors II, VII, IX, X, concentrate) (C) (2, 8)	(dried)
13. Cardiovascular Drugs		
13.1 *Antianginal drugs*		
glyceryl trinitrate		tablet (sublingual) 0.5 mg
isosorbide dinitrate (1)		tablet (sublingual) 5 mg
propranolol (1)		tablet, 10 mg, 40 mg (hydrochloride) injection, 1 mg (hydrochloride) in 1 ml ampoule
13.2 *Antiarrhythmic drugs*		
lidocaine		injection, 20 mg (hydrochloride)/ml in 5 ml ampoule
procainamide (1)		tablet, 500 mg (hydrochloride) injection, 100 mg (hydrochloride)/ml in 10-ml ampoule
propranolol (1)		tablet, 10 mg, 40 mg (hydrochloride) injection, 1 mg (hydrochloride) in 1-ml ampoule
	quinidine (A, B) (1)	tablet, 200 mg (sulfate)
13.3 *Antihypertensive drugs*		
hydralazine (1)		tablet, 50 mg (hydrochloride)
hydrochlorothiazide (1)		tablet, 50 mg
propranolol (1)		tablet, 40 mg (hydrochloride)
sodium nitroprusside (1, 2, 8)		injection, 10 mg/ml in 5 ml vial
	methyldopa (A, B) (7)	tablet, 250 mg
	reserpine (A) (1, 7)	tablet, 0.1 mg, 0.25 mg injection, 1 mg in 1-ml ampoule
13.4 *Cardiac glycosides*		
digoxin (4)		tablet, 0.0625 mg, 0.25 mg oral solution, 0.05 mg/ml injection, 0.25 mg/ml in 2 ml ampoule
	digitoxin (B) (6)	tablet, 0.05 mg, 0.1 mg oral solution, 1 mg/ml injection, 0.2 mg in 1 ml ampoule
13.5 *Drugs used in shock or anaphylaxis*		
dopamine (2)		injection, 40 mg (hydrochloride)/ml in 5 ml vial
epinephrine[1]		injection, 1 mg (as bitartrate) in 1 ml ampoule[1]
	isoprenaline (C)	injection, 1 mg (hydrochloride)/ml in 2 ml ampoule

[a] When the strength is specified in terms of a selected salt or ester, this is mentioned in brackets; when it refers to the active moiety, the name of the salt or ester in brackets is preceded by the word "as".

[1] Levo-(–)-isomer.

Main list	Complementary drugs	Route of administration, pharmaceutical forms and strengths[a]
14. Dermatological Drugs		
14.1 *Antiinfective drugs*		
neomycin + bacitracin (1)		ointment, 5 mg neomycin + 500 IU bacitracin zinc/g
14.2 *Antiinflammatory drugs*		
betamethasone (1, 3)		ointment or cream, 0.1%[a] (as valerate)
hydrocortisone (1)		ointment or cream, 1%[a] (acetate)
14.3 *Astringents*		
aluminium acetate		solution 13%[a] for dilution
14.4 *Fungicides*		
benzoic acid + salicylic acid		ointment or cream, 6%[a] + 3%[a]
miconazole (1)		ointment or cream, 2%[a] (nitrate)
nystatin		ointment or cream, 100 000 IU/g
14.5 *Keratoplastic agents*		
coal tar		solution, topical 20%[a]
salicylic acid		solution, topical 5%[a]
14.6 *Scabicides and pediculicides*		
benzyl benzoate		lotion, 25%[a]
gamma benzene hexa chloride		cream or lotion, 1%[a]
15. Diagnostic Agents		
edrophonium (2, 8)		injection, 10 mg (chloride) in 1 ml ampoule
tuberculin, purified protein derivative (PPD)		injection
15.1 *Ophthalmic*		
fluorescein		eye drops, 1% (sodium salt)
15.2 *Radiocontrast media*		
adipiodone meglumine (1)		injection, 25%[a] in 20 ml vial
barium sulfate (1)		powder
iopanoic acid (1)		tablet, 500 mg
meglumine amidotrizoate (1)		injection, 60%[a] in 20 ml ampoule
sodium amidotrizoate (1)		injection, 50%[a] in 20-ml ampoule
16. Diuretics		
amiloride (1)		tablet, 5 mg (hydrochloride)
furosemide (1)		tablet, 40 mg injection, 10 mg/ml in 2-ml ampoule
hydrochlorothiazide (1)		tablet, 50 mg
mannitol		injectable solution, 10%[a], 20%[a]
	chlortalidone (B) (6)	tablet, 50 mg
17. Gastrointestinal Drugs		
17.1 *Antacids* (nonsystemic)		
aluminium hydroxide		tablet, 500 mg oral suspension, 320 mg/5 ml
magnesium hydroxide		oral suspension, equivalent to 550 mg magnesium oxide/10 ml
	calcium carbonate (A, B)	tablet, 600 mg
17.2 *Antiemetics*		
promethazine (1)		tablet, 10 mg, 25 mg (hydrochloride) elixir or syrup, 5 mg (hydrochloride)/5 ml injection, 25 mg (hydrochloride)/ml in 2 ml ampoule
17.3 *Antihaemorrhoidals*		
local anaesthetic, astringent and antiinflammatory drug (1)		ointment or suppository

[1] Levophrine is the (–)isomer. Appropriate dosage adjustment is required when the uraemic form (isoprenefrine) is used.

Main list	Complementary drugs	Route of administration, pharmaceutical forms and strengths[a]	
17. Gastrointestinal Drugs *(continued)*			
17.4 *Antispasmodics*			
ropine (1)		tablet, 1 mg (sulfate) injection, 1 mg (sulfate) in 1-ml ampoule	
17.5 *Cathartics*			
enna (1)		tablet, 7.5 mg (sennosides)	
17.6 *Diarrhoea*			
17.6.1 *Antidiarrhoeal*			
odeine (1?10)		tablet, 30 mg (phosphate)	
17.6.2 *Replacement solution*			
oral rehydration salts (for glucose-salt solution)			
For 1 litre of water:		(sachet)	mmol/l
sodium chloride (table salt)		3.5 g, Na^+	90
sodium bicarbonate (baking soda)		2.5 g, HCO_3^-	30
potassium chloride		1.5 g, K^+	20
glucose (dextrose)		20.0 g, glucose	111
18. Hormones			
18.1 *Adrenal hormones and synthetic substitutes*			
dexamethasone (1)		tablet, 0.5 mg, 4 mg injection, 4 mg (sodium phosphate) in 1-ml ampoule	
hydrocortisone		powder for injection, 100 mg (as sodium succinate) in vial	
prednisolone (1)		tablet, 5 mg	
	fludrocortisone (c)	tablet, 0.1 mg (acetate)	
18.2 *Androgens*			
testosterone (2)		injection, 200 mg (enantate) in 1 ml ampoule injection 25 mg (propionate) in 1 ml ampoule	
18.3 *Estrogens*			
ethinylestradiol (1)		tablet, 0.05 mg	
18.4 *Insulins*			
compound insulin zinc suspension (1)		injection, 40 IU/ml in 10 ml vial, 80 IU/ml in 10-ml vial	
insulin injection		injection, 40 IU/ml in 10 ml vial, 80 IU/ml in 10-ml vial	
18.5 *Oral contraceptives*			
ethinylestradiol + levonorgestrel (1)		tablet, 0.03 mg + 0.15 mg, 0.05 mg + 0.25 mg	
ethinylestradiol + norethisterone (1)		tablet, 0.05 mg + 1.0 mg	
	norethisterone (8)	tablet 0.35 mg	
18.6 *Progestogens*			
norethisterone (1)		tablet, 5 mg	
18.7 *Thyroid hormones and antagonists*			
levothyroxine		tablet, 0.05 mg, 0.1 mg (sodium salt)	
potassium iodide		tablet, 60 mg	
propylthiouracil (1)		tablet, 50 mg	
18.8 *Ovulation inducer*			
	clomifene (c) (2,8)	tablet, 50 mg (citrate)	

Main list	Complementary drugs	Route of administration pharmaceutical forms and strengths[a]	
19. Immunologicals			
19.1 *Sera and immunoglobulins*			
anti-D immunoglobulin (human)		injection, 0.25 mg/ml	
antirabies hyperimmune serum		injection, 1000 IU in 5 ml ampoule	
antivenom sera		injection	
diphtheria antitoxin		injection, 10 000 IU, 20 000 IU in vial	
immunoglobulin, human normal (2)		injection	
tetanus antitoxin		injection, 50 000 IU in vial	
19.2 *Vaccines*			
19.2.1 *For universal immunization*			
BCG vaccine (dried)		injection	All vaccines should comply with the WHO Requirements for Biological Substances[c]
diphtheria-pertussis-tetanus vaccine		injection	
diphtheria-tetanus vaccine		injection	
measles vaccine		injection	
poliomyelitis vaccine (live attenuated)		oral solution	
smallpox vaccine		multiple puncture	
tetanus vaccine		injection	
19.2.2 *For specific groups of individuals*			
influenza vaccine		injection	
meningococcal vaccine		injection	
rabies vaccine		injection	
typhoid vaccine		injection	
yellow fever vaccine		injection	
20. Muscle Relaxants (Peripherally Acting) and Cholinesterase Inhibitors			
neostigmine (1)		tablet, 15 mg (bromide) injection, 0.5 mg (metilsulfate) in 1-ml ampoule	
suxamethonium (2)		injection, 50 mg (chloride)/ml in 2-ml ampoule	
tubocurarine (1,2)		injection, 10 mg (chloride)/ml in 1.5 ml ampoule	
	pyridostigmine (8) (2,8)	tablet, 60 mg (bromide) injection, 1 mg (bromide) in 1-ml ampoule	
21. Ophthalmological Preparations			
21.1 *Anti-infective*			
silver nitrate		solution (eye drops) 1%	
sulfacetamide		eye ointment, 10% (sodium salt) solution (eye drops), 10% (sodium salt)	
tetracycline (1)		eye ointment, 1% (hydrochloride)	
21.2 *Anti-inflammatory*			
hydrocortisone (2,7)		eye ointment, 1% (acetate)	
21.3 *Local anaesthetics*			
tetracaine (1)		solution (eye drops), 0.5% (hydrochloride)	
21.4 *Miotics*			
pilocarpine		solution (eye drops), 2%, 4% (hydrochloride or nitrate)	

[a] When the strength is specified in terms of a selected salt or ester, this is mentioned in brackets; when it refers to the active moiety, the name of the salt or ester is preceded by the word "as".

[c] Dried BCG Vaccine (Revised 1979) (WHO Technical Report Series, No. 638, 1979); Diphtheria Toxoid, Pertussis Vaccine, Tetanus Toxoid and Combined Vaccines (Revised 1978) (WHO Technical Report Series, No. 638 [illegible] WHO Technical Report Series, No. 329, 1966) [illegible] (WHO Technical Report Series, No. 486 [illegible] (WHO Technical Report Series, No. 323, 1966); Tetanus Toxoid (Revised [illegible]) (WHO Technical Report Series, No. 638, 1979); Influenza Vaccine (Inactivated) (Revised 1978) (WHO Technical Report Series, No. 594, 1976); Addendum 1977 [illegible] Meningococcal Polysaccharide Vaccine (WHO Technical Report Series, No. 594, 1976) [illegible] (WHO Technical Report Series, No. 626, 1978); Rabies Vaccine for Human Use (WHO [illegible]) (WHO Technical Report Series, No. 530, 1973); Revision available 1980; Typhoid Vaccine (WHO Technical Report Series, No. 361, 1967); Yellow Fever Vaccine (Revised 1975) (WHO Technical Report Series, No. 594, 1976).

Main list	Complementary drugs	Route of administration, pharmaceutical forms and strengths[a]
		21.5 *Mydriatics*
homatropine (L)		solution (eye drops), 2% (hydrobromide)
	epinephrine (A, B) (3)	solution (eye drops), 2% (as hydrochloride)
		21.6 *Systemic*
acetazolamide		tablet, 250 mg
		22. Oxytocics
ergometrine (L)		tablet, 0.2 mg (maleate) injection, 0.2 mg (maleate) in 1-ml ampoule
oxytocin		injection, 10 IU in 1-ml ampoule
		23. Peritoneal Dialysis Solution
intraperitoneal dialysis solution (of appropriate composition)		parenteral solution
		24. Psychotherapeutic Drugs
amitriptyline (L)		tablet, 25 mg (hydrochloride)
chlorpromazine (L)		tablet, 100 mg (hydrochloride) syrup, 25 mg (hydrochloride)/5 ml injection, 25 mg (hydrochloride)/ml in 2-ml ampoule
diazepam (L)		tablet, 5 mg
fluphenazine (L, S)		injection, 25 mg (decanoate or enanthate) in 1-ml ampoule
haloperidol (L)		tablet, 2 mg injection, 5 mg in 1-ml ampoule
lithium carbonate (2, 4, 7)		capsule or tablet, 300 mg
		25. Respiratory Tract, Drugs Acting on the
		25.1 *Antiasthmatic drugs*
aminophylline (L)		tablet, 200 mg injection, 25 mg/ml in 10-ml ampoule
epinephrine		injection, 1 mg (as hydrochloride) in 1-ml ampoule
salbutamol (L)		tablet, 4 mg (sulfate) oral inhalation (aerosol), 0.1 mg (sulfate) per dose syrup, 2 mg (sulfate)/5 ml
	beclometasone (B) (8)	oral inhalation (aerosol), 0.05 mg (dipropionate) per dose
	cromoglicic acid (B) (2, 8)	oral inhalation (cartridge), 20 mg (sodium salt) per dose
	ephedrine (A)	tablet, 30 mg (as hydrochloride) elixir, 15 mg (as hydrochloride)/5 ml injection, 50 mg (sulfate) in 1-ml ampoule

Main list	Complementary drugs	Route of administration, pharmaceutical forms and strengths[a]
		25.2 *Antitussives*
codeine (10)		tablet, 10 mg (phosphate)
		26. Solutions Correcting Water, Electrolyte and Acid-Base Disturbances
		26.1 *Oral*
oral rehydration salts (for glucose salt solution)		For composition, see 17.6.2 *Replacement solution*
potassium chloride		oral solution
		26.2 *Parenteral*
compound solution of sodium lactate		injectable solution
glucose		injectable solution, 5% isotonic, 50% hypertonic
glucose with sodium chloride		injectable solution, 4% glucose, 0.18% sodium chloride (Na^+ 30 mmol, Cl^- 30 mmol/l)
potassium chloride		injectable solution
sodium bicarbonate		injectable solution, 1.4% isotonic (Na^+ 167 mmol/l, HCO_3^- 167 mmol/l)
sodium chloride		injectable solution, 0.9% isotonic (Na^+ 154 mmol/l, Cl^- 154 mmol/l)
water for injection		in 2 ml, 5 ml, 10 ml ampoules
		27. Surgical Disinfectants
chlorhexidine (L)		solution, 5% (gluconate) for dilution
iodine (L)		solution, 2.5%
		28. Vitamins and Minerals
ascorbic acid		tablet, 50 mg
ergocalciferol (L)		capsule or tablet, 1.25 mg (50 000 IU) oral solution, 0.25 mg/ml (10 000 IU)
nicotinamide (L)		tablet, 50 mg
pyridoxine		tablet, 25 mg (hydrochloride)
retinol		capsule or tablet, 7.5 mg (25 000 IU), 60 mg (200 000 IU)[b] oral solution, 15 mg/ml (50 000 IU)
riboflavin		tablet, 5 mg
sodium fluoride		tablet, 1.1 mg
thiamine		tablet, 50 mg (hydrochloride)
	calcium gluconate (C) (2, 8)	injection, 100 mg/ml in 10-ml ampoule

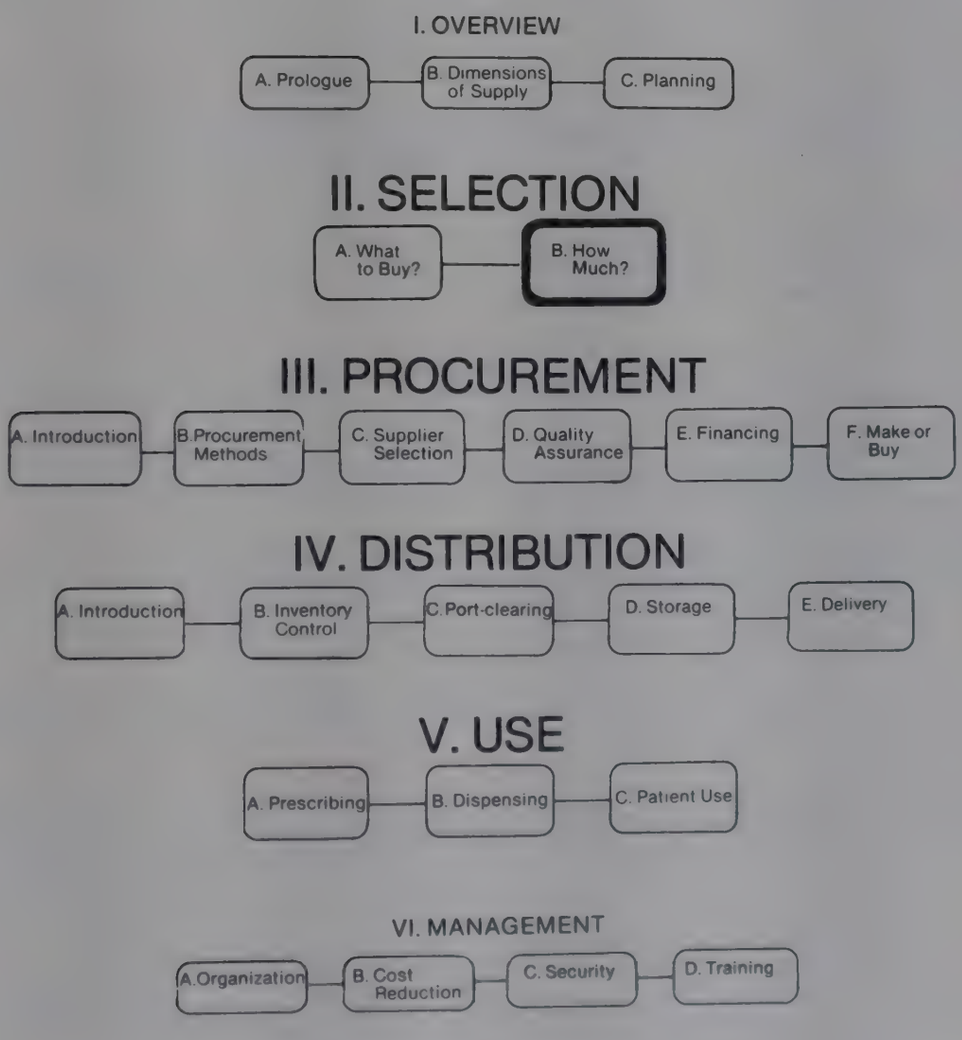
[a] When the strength is specified in terms of a selected salt or ester, this is mentioned in brackets; when it refers to the active moiety, the name of the salt or ester is preceded by the word "as".

[b] For use in the treatment of xerophthalmia with a single dose, not to be repeated before 4 months have elapsed.

Reprinted with permission from *WHO Technical Report Series*, No. 641, 1979.

Chapter II.B.

How Much to Buy: Predicting Drug Requirements



	Page
1. GENERAL PRINCIPLES	81
2. THREE METHODS FOR ESTIMATING DRUG REQUIREMENTS	82
a. Population-Based Estimates	82
b. Service-Based Estimates	87
c. Consumption-Based Estimates	90
3. MAINTAINING ADEQUATE DRUG QUANTITIES	93
a. Information Systems	93
b. Pipeline Considerations	93
c. Impact of Lead Time	94
d. Reconciling Needs and Funds	95
e. Anticipating Losses	96
SUMMARY	96
REFERENCES	97

How Much to Buy: Predicting Drug Requirements

In an established adequately funded drug supply system the determination of drug requirements is usually a matter of systematically monitoring stock levels and regularly replenishing drug supplies as they are consumed. But when a new drug supply program is being established, when an existing program is being reorganized, or when current consumption patterns suggest inefficient or irrational drug use, then a more methodical approach to determining drug requirements is needed. This chapter will review basic principles of drug selection, describe and illustrate the three methods of estimating drug requirements, and summarize some key points for the maintenance of adequate drug supplies.

1. GENERAL PRINCIPLES

Chapter II.A. describes the issues involved in drug selection. Some of them impact heavily on determining order quantities and are worth highlighting here.

(1) Select the minimum number of drugs needed to treat the most important diseases that are identified on the basis of epidemiology of the target population.

(2) Select only generically named drugs rather than multiple brand names of the same drugs.

(3) Select only those dosage forms of each drug which are necessary.

(4) Develop drug lists for each level of the system, and make them uniform for each problem treated (level-of-use categories).

(5) Develop standard norms for treatment in order to increase the consistency of drug use and to reduce the number of drugs needed for each clinical situation.

Given these principles, there are three basic methods for estimating drug quantities:

- Population-based: Survey and/or estimate the prevalence of various conditions in the population and, based on accepted or devised treatment norms, estimate drugs needed to treat the population.

- Service-based: Determine the number and types of health providers available and the diseases they will be likely to treat. Based on the amount of services provided, quantities are estimated.

- Consumption-based: Gather information from commercial sources (where available), private voluntary organizations, or government programs on previous drug utilization.

Figure II.B.1. illustrates the three approaches. Population-based methods estimate drug needs based on the ideal amount required to meet the major health needs of the population. Service-based methods estimate the actual amount of services that will be provided by the health program, and the quantities of drugs needed to provide these services. Consumption-based estimates are basically historical, relying on demands placed on the system through past experience.

Needs versus Wants

These methods are designed to separate needs from wants. Unfortunately, the types and quantities of drugs purchased for public health programs all too frequently reflect the personal preferences of key decision-makers, or the demands placed on the system by health providers. This process may not reflect the true needs of the health system. For example, it is common to find a ministry purchasing large quantities of an expensive broad spectrum antibiotic, because the health professionals prefer to use it in all situations, rather than larger quantities of simple, less-expensive antibiotics with more specific indications for use. An analysis of this type may show that Penicillin or Sulfa antibiotics would serve the needs of the system better than ampicillin. Such selection decisions need to be made by the formulary committee and will have profound effects on purchase quantities of each individual drug.

Standard Norms for Treatment

As the remainder of the chapter will demonstrate, population-based and service-based estimation techniques rely heavily on the development of standard norms for treatment, and the use of such treatment norms can improve drug use when consumption-based estimates are used. Thus, the concept of establishing standard norms for treatment is worth emphasizing.

Most diseases can be treated using standard therapeutic regimens. These regimens should be established as guidelines by the formulary committee, in consultation with various normative program offices. They are not intended to be fixed regimens that do not allow deviation, although the amount of deviation allowed will depend on training and experience. Clearly a doctor who treats more severe forms of illness and has more training can deviate more than an auxiliary nurse working in a health post. Nevertheless, it should be decided in advance that, for example, effective treatment for streptococcal disease is Penicillin G 400,000 units three times a day for ten days, or that two liters of oral rehydration solution will treat most cases of diarrhea.

2. THREE METHODS FOR ESTIMATING DRUG REQUIREMENTS

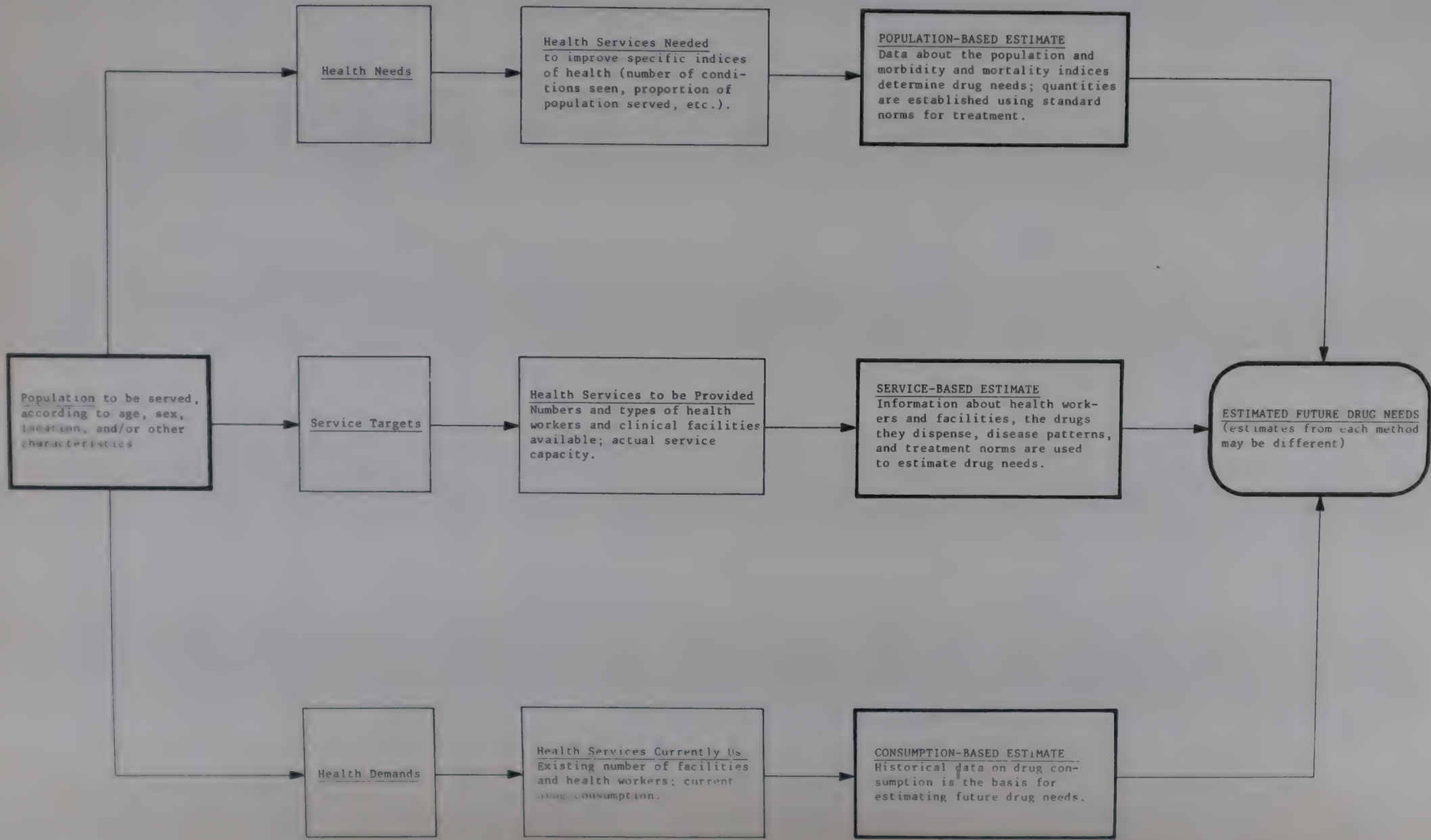
The following discussion presents the procedures, and the advantages and disadvantages, for each of the estimation methods illustrated in Figure II.B.1.

a. Population-Based Estimates

This method for estimating drug quantities starts with an epidemiological

Figure II.B.1.

Three Methods of Estimating Drug Requirements


Health Needs
Health Services Needed
to improve specific indices of health (number of conditions seen, proportion of population served, etc.).
POPULATION-BASED ESTIMATE
Data about the population and morbidity and mortality indices determine drug needs; quantities are established using standard norms for treatment.
Population to be served, according to age, sex, location, and/or other characteristics
Service Targets
Health Services to be Provided
Numbers and types of health workers and clinical facilities available; actual service capacity.
SERVICE-BASED ESTIMATE
Information about health workers and facilities, the drugs they dispense, disease patterns, and treatment norms are used to estimate drug needs.
ESTIMATED FUTURE DRUG NEEDS
(estimates from each method may be different)
Health Demands
Health Services Currently Us
Existing number of facilities and health workers; current drug consumption.
CONSUMPTION-BASED ESTIMATE
Historical data on drug consumption is the basis for estimating future drug needs.

assessment of a country's most important diseases and health problems. Since the first step involves analyzing existing morbidity and mortality data, this method is only as valid as the data base. Some countries are fortunate and have already completed statistically valid health surveys that can show the true prevalence of disease at the community level. Other sources of data include routinely collected health statistics from hospitals and health centers, studies conducted as part of pilot or experimental health projects, and statistics from international agencies such as WHO, the World Fertility Survey, or bilateral donors.

The goal of this epidemiological data analysis is to establish as objectively as possible the true health needs of the target population. This method works best when a country is planning an ambitious health program that intends to cover populations that have not been well served in the past, where there is little prior experience on which to base consumption estimates, and where the major goals are set as measurable reductions in morbidity and mortality. This method will not work well where the available data on health status is sketchy, is widely variable by region, or is otherwise inaccurate.

Estimates of drug quantities using this approach determine the theoretical "ideal" for a population, and are usually the most generous quantities of the three methods available. This has value where resources are likewise generous and helps cover "leakage" that invariably occurs within the system. However, it may also encourage wastage and/or graft unless specific plans are made to control this problem. If resources for purchasing drugs are limited, this method may not be the most appropriate. It could work, however, if the epidemiological problems are prioritized and a limited number selected as "target-diseases" for control.

Method

The following description illustrates the method for population-based estimates:

(1) Assume a population of one million people living in a "typical" region of the country.

(2) Determine the demographic composition of that basic population count. In general, appropriate age groupings are children 0-4 years; children 5-14 years; women aged 15-44 years; men aged 15-44 years; adults over 45 years. This ensures coverage of the high priority maternal/child age group. However, other program priorities may dictate other groupings (e.g., under 1 and 1-4 are common groupings as well). Keep the number of divisions as simple as possible; the larger the number of age groups, the more complex is the work that needs to be done.

(3) Determine the morbidity/mortality rates for the specified age groups using the data sources discussed above, and convert into estimated attack rates for each disease.

(4) Calculate the frequency of occurrence of each disease in a year's time for the population of one million. For example, suppose data show that children aged 0-4 average 3 severe attacks of diarrhea per year, and the population pyramid shows the population of one million has

160,000 children aged 0-4, then the number of diarrhea attacks that need treatment for this age group are 160,000 x 3, or 480,000. Similar calculations should be done for diarrhea attack rates for each of the other age groups, to arrive at the total number of diarrheal episodes that need treatment in one year for a population of one million. This same calculation should be repeated for each of the other high priority health problems.

(5) Using these specific morbidity/mortality rates, estimate the type and frequency of treatment required for each health problem. For example, in order to treat diarrhea, estimates could be made that 90% of cases can be treated by oral rehydration and 10% of cases require intravenous fluids. In addition, 5% of cases may require metronidazole for acute amoebiasis, and 10% may require antibiotics for bacillary dysentery or cholera. Obviously, the exact percentages depend on the epidemiology of the area. As previously mentioned, wide regional variations make this process cumbersome, since individual calculations need to be done for each region.

(6) Use the standard norms for treatment previously developed to calculate the quantities of each dosage of drug needed to treat each disease. For our example of diarrheal disease, if the treatment norms estimate 2 liters of oral rehydration fluid are required for each case of severe diarrhea, and the salts are packaged in packets that reconstitute to make one liter, then 864,000 packets of oral rehydration salts will be required to treat all cases of severe diarrhea in children age 0-4 in a population of one million people (160,000 children aged 0-4 x 3 severe attacks of diarrhea/year x 2 packs of oral salts/attack x .90 proportion of diarrhea attacks treatable by oral salts = 864,000).

These calculations need to be repeated for each treatment regimen for each disease. It is easier to calculate these numbers using the combined disease rates for all age groups, but individual age group breakdowns can be done if one is willing to put in the effort. This is especially helpful if, as usually happens, resource limitations prevent purchasing enough drugs for all age groups and the groups must be prioritized. It will be helpful to know what quantities each age group will require.

(7) Add to the quantities calculated the additional amounts required to fill the pipeline and to cover wastage.

(8) Multiply this amount by the number of units of one million population the health program seeks to serve.

This total thus indicates the ideal quantity of drugs needed to treat all the high priority health problems in the specified target population. These calculations have value if only to indicate the huge quantity of drugs required if an ideal health system could be developed and utilized. It is also a good means to convince policy makers of the near impossibility of a "free" system, with the government aspiring to meet all health needs directly. Since reality is less than perfection, one of the remaining two methods is most often used to calculate drug quantities.

An example of population-based estimates of drug needs for a rural health

Country Study II.B.1.

Population-Based Estimates of Drug Needs in Haiti

A. Epidemiological Estimates of Disease Prevalence Combined with Standard Norms for Treatment

	ILLNESS	GROUP	REQUIRING THERAPY	DRUGS USED	PER PATIENT
1.	Diarrhea	0-4	3 severe episodes per year	a. Oral therapy in 100% b. Ringer's Lactate in 5% c. Metronidazole	a. 2 liters b. 1 liter c. 250 mg x 3/day for 5 days
		5-9	1 severe episode per year	a. Oral therapy in 20% b. Ringer's Lactate in 1% c. Metronidazole	a. 2 liters b. 2 liters c. 500 mg x 3/day for 5 days
		over 10	0.5 episodes/year	a. IV & oral fluids in 1% b. Metronidazole	a. 2 liter & 6 liters b. 750 mg x 3/day for 5 days
2.	Pneumonia	0-4	0.5 bouts/year	a. Penicillin V syrup in 80% b. Procain Penicillin G 20%	a. 200,000 units x 3/day for 5 days b. 600,000 units (daily injection x 3 days)
		5-9	0.1 bout/year	a. Penicillin V tablets in 80% b. Procaine Penicillin G 20%	a. 400,000 units x 3/day for 5 days b. 1.2 million units (daily injection x 3 days)
		over 10	.01 bout/year	a. Penicillin V tablets in 80% b. Procaine Penicillin G 20%	a. 400,000 units x 3/day for 5 days b. 2.4 million units (daily injection x 3 days)
3.	URI and Influenza	0-4	3 bouts/year	a. Cough mixture	a. one ounce (28 gm)
		5-9	2 bouts/year	a. Cough mixture b. Phenylephrine drops	a. one counce (28 gm) b. 2 cc drops
		over 10	1 bout/year	a. Cough mixture b. Phenylephrine drops	a. one ounce (28 gm) b. 2 cc drops
4.	Intestinal	0-4	100% ascaris treated x 4/yr	a. Piperazine	a. 1 gram/day for 2 days
5.	Otitis Media	0-4	1 bout/year (C,G)	a. Penicillin V syrup 80% b. PAM Penicillin G 20%	a. 200,000 units x 3/day for 5 days b. 600,000 units PAM Pen. G (single injection)
⋮	⋮	⋮	⋮	⋮	⋮

B. Drug Ouantities Required to Treat High-Priority Diseases

NAME OF DRUG	UNIT	USED FOR	TOTAL NO. OF UNITS FOR 1,000,000 PERS/YEARS		TOTAL NO. OF UNITS FOR INITIAL PROCUREMENT 1,000,000 PERS/14 MONTHS PLUS 30% MARGIN FOR LOSS
Oral Rehydration Salts	1 liter packet	diarrhea rehydration	1,005,600		1,525,160
Ringer's	500 cc bottles	IV rehydration	67,200		98,112
Metronidazole	250 mg. tablets	amebiasis	270,000		394,200
Penicillin V tablets	200,000 unit tablets	pneumonia otitis media exudative tonsilitis impetigo	460,800 1,440,000 3,554,000 252,000	5,506,800	8,039,928
Penicillin V Syrup	80 cc bottles 250 mg/scc	pneumonia otitis media exudative tonsilitis impetigo	60,000 120,000 135,000 10,500	325,500	475,230
Procaine Penicillin G injectable	(3,000,000 units) 10 cc vials	pneumonia gonorrhea syphilis	15,396 9,600	25,536	37,283
Phenylephrine	30 cc bottle	decongestant for URI (topical)	216,000		315,360
Cough Mixture	1 gallon containers	cough	11,250		16,425
⋮	⋮	⋮	⋮		⋮

program in Haiti is presented in Country Study II.B.1. These estimates were done by officials of the Department of Health and Population in conjunction with technical advisors. The final amounts shown served as a discussion point for officials to review goals and objectives of the program and they were adjusted downwards to match the resources available. The tables shown provide only a partial list of the drugs involved -- in all, 42 drugs were included to treat 43 different conditions of major rural health concerns.

b. Service-Based Estimates

These estimates of drug quantities are based on the number of services that will be provided by the program(s). This approach incorporates the technical, financial, administrative, and cultural constraints in the logistics plan, and results in a quantity lower than the population-based estimates. Some observers feel this is a more "realistic" target amount, one that presents a "truer picture" of what the health system can do.

However, service-based estimates reflect only those patients who seek attention, and does not estimate the true need of all the target population. Physical inaccessibility or cultural barriers to health care may prevent patients who really should seek services from doing so and, therefore, drug orders may reflect only the problems of the more accessible population. As the health program expands services to more inaccessible people, service-based estimates may be inaccurate.

One way to minimize this problem is to set service targets as a percent of the known health problems, e.g., the health program will treat 50% of all severe cases of diarrhea. This method combines the service and population-based estimates, using the model presented in the previous section but with final quantities adjusted downwards to reflect these targets.

Another method is to look at what problems current health providers are treating and estimate the drugs needed for these; then calculate the quantities of drugs needed by multiplying by the number of providers projected for the new program. This method presupposes two critical factors:

- that some experience already exists in providing services;
- that information exists on the types of services given.

If the program is completely new, or the type of health worker is new (e.g., village health worker), or no information on services is available, then this method will not work. Implementation of this methodology is outlined below.

Method

(1) Review service registers for each type of facility (e.g., hospital, health center, health post, etc.) or each type of provider (doctor, nurse, auxiliary, sanitarian, village health worker, etc.) and tabulate the 25 most common diagnoses and note their frequency of occurrence. This will usually cover about 75% of the problems seen by any facility or provider. This review should cover an entire year, since seasonal variations (winter/summer or wet/dry) can markedly alter service patterns. Thus, if service registers do not exist, it will take a

Country Study II.B.2.

Service-Based Estimates of Drug Quantities in Afghanistan

In Afghanistan prior to 1975 the approximately 100 operational Basic Health Centers (BHCs) were supplied with drugs once a year according to standard list "A" (densely populated areas) or standard list "B" (less populated areas). No provision existed for the interim resupply or in-province redistribution of drugs.

The use of a standard list meant that annual resupply was independent of use or local disease pattern. Thus, except for the difference in quantities between list "A" and list "B", no provision was made to link drug supply to annual patient load or number of active sub-centers. The standard lists "A" and "B" had been in use for some years without revision, and appeared to have been developed principally on the basis of surplus inventories at the General Medical Depot. This system had the following major disadvantages:

1. A considerable wastage of some drugs resulted from supply levels in excess of demand. In all centers, large amounts of outdated and spoiled tablets, ampules, and vaccines had to be removed from inventory.

2. Active centers rapidly ran out of important drugs, leading to a decreased ability to treat patients and considerable frustration of the professional staff. In economic terms, this increased the cost per treated patients, since the total overhead can only be applied to patients adequately treated.

3. A tendency to reduce the dose prescribed for a specific illness to such small amounts that cure was unlikely, and, also, the use of drugs in plentiful supply as placebo or as a substitute for the correct treatment.

In 1976, the Ministry of Health developed an improved logistics system with the following components:

1. A new list of 42 basic drugs, determined in advance to cover approximately 90% of the most common complaints.

2. Drugs supplied to each BHC in a quantity estimated to cover one year's consumption.

3. A drug usage chart with indications, common usage, and dosages. (See below.)

4. Development of technical instructions in the form of logical flow diagrams to increase the probability of correct diagnosis and treatment. This was produced as a much needed reference help, considering the limited medical skill of the paramedical staff and the limited diagnostic facilities of the BHCs.

5. Distribution of drugs, primarily in prepackaged form, to the doctor, auxiliary nurse midwife, and the male nurse according to skill level and category of patients seen (as specified in the BHC Task Description Chart and job descriptions).

This was accomplished in the following manner:

To ascertain the disease pattern reflected in the diagnoses recorded, random samples were drawn from all health service registers in the six pilot health centers (total 1207 diagnoses). Sample size from each staff member was in direct proportion to the total number of patients seen by each category of health worker. In order to ascertain seasonal patterns, sampling was done twice -- once to reflect the winter period and once to reflect the summer. Diagnoses were not broken down by age and sex. The following table provides a frequency distribution of the most common diseases treated during the project.

Ten Most Common Diagnoses, Winter/Summer

	WINTER		SUMMER	
1.	Common Cold	10%	Diarrhea and Dysentery	13%
2.	Dyspepsia and Gastritis	9%	Dyspepsia and Gastritis	8%
3.	Conjunctivitis	8%	Good health	7%
4.	Rheumatism	7%	Rheumatism and Lumbago	6%
5.	Anemia	6%	Conjunctivitis	5%
6.	Pregnancy and Childbirth	5%	Family Planning	4%
7.	Cough	5%	Pregnancy	3%
8.	Pneumonia	4%	Cough	3%
9.	Wounds	4%	Bronchitis	3%
10.	Good health	3%	Headache	3%

The 10 most common diagnoses accounted for 57% of all diagnoses made.
The 25 most common diagnoses accounted for 84% of all diagnoses made.

Country Study II.B.2. (continued)

These diagnostic frequencies were then compared with the standard treatment norms in the Drug Usage Chart (see below) to calculate drug quantities needed to supply 100 BHCs. Using costs per unit of drug, the total costs of supplying drugs to BHCs was calculated. The final table appeared like this:

	DRUG	UNIT	TOTAL ESTIMATED QUANTITY FOR 100 BHCs	UNIT PRICE	TOTAL COST U.S.$
1.	Chloroquine 150 mg.	Tablet	140,000	7.41/1,000	1,037.00
2.	Chloroquine 100 mg.	Tablet	0	0	0
3.	Ferrous sulphate 300 mg.	Tablet	3,100,000	.74/1,000	2,294.00
4.	Folic acid 5 mg.	Tablet	2,900,000	1.25/1,000	3,625.00
5.	GE-solution 1 liter	Powder	70,000	0.45/1.	31,500.00
6.	INH/Thiazetazone 300/150 mg.	Tablet	600,000	8.44/1,000	5,064.00
7.	Iron dextran	Vials	10,000	0.42/vial	4,200.00
8.	Methyl-ergometrine	Tablet	220,000	6.18/1,000	1,359.60
	•	•	•	•	•
	•	•	•	•	•
	•	•	•	•	•

Drug Usage Chart

NO.	Medicine/Unit	No. Tabs.	Used For	Common Dosage
1.	Chloroquine 150 mg. tab (base)	10	Malaria in adults (adequate alone in Falciparum)	Cure: 4+2 tabs first day, then 2 tabs for 2 days. Prevention: 2 tabs. once weekly
2.	Chloriquine 100 mg. tab (base)	--	Malaria in children (adequate alone in Falciparum)	Cure: 10 mg/kg (body weight) in 2 doses daily for 4 days. Prevention: 1/2-1 tab. once weekly
3.	Ferrous Sulphate 300 mg. tab.	30	Iron deficiency anemia (especially in maternal care)	Adults: 1-3 daily, 1 to 3 months. Children: 1 tab. daily for 1 to 3 months
4.	Folic Acid 5 mg tab.	30	Folate-deficiency anemia (especially in maternal care)	Adults: 1 tab daily for 1 to 3 months
5.	Glucose-electrolyte powder. Dissolve packet to 1 l (or 3 l) solution.	--	Rehydratin in diarrhea (especially in children)	Ab libitum, 2-3 liters/day, 1 to 3 days
6.	INH/Thiacetazone 300/150 mg.	30	Tuberculosis	SE Special TB Treatment Scheme
7.	Iron-Dextran 10cc vial	--	Severe iron deficiency anemia	Adults only: 2 ml. daily 5 days, followed by tablet, or 8 ml. in 2 doses (4 ml. in each buttock)
8.	Methyl Ergometrine 0.2 mg. vials	9	Mild post-partum bleeding	Adults: 1 tablet 3 times daily, 3 days
	•	•	•	•
	•	•	•	•
	•	•	•	•
39.	Whitfield's Ointment	1 oz. tube	Fungus skin infection	Apply daily until clear
40.	Zinc Oxide Ointment	1 lb. jar	Non-specific dressing of superficial wounds, burns	Apply daily until relief

minimum of one year's experience to gain enough information to use this method.

(2) Establish standard norms for treatment, as outlined in the basic principles section. This estimating method cannot proceed further without these norms.

(3) Calculate the quantities of drugs needed on a yearly basis by each facility or provider by multiplying the number of cases of a particular problem seen in a year by the quantity of the drug used to treat that problem. Do this for all 25 of the identified health problems for each type of facility or provider.

(4) Calculate the total quantity of drugs needed to supply all the facilities and/or providers projected by the program. The quantities should be phased to meet the anticipated start-up of program activities, i.e., if X number of health centers (health posts, nurse auxiliaries, etc.) will be completed by Year 2, then include the quantity of drugs they will need in Year 1 estimates (see discussions on supply time and pipeline).

Country Study II.B.2. illustrates the use of service-based estimates in Afghanistan.

c. Consumption-Based Estimates

Consumption-based estimates are useful where good historical data on drug consumption exists, and where demand for program services has reached a steady state. This method also requires a reasonably accurate information system that records inventory levels over periods of time (at least a year to include seasonal variations). If these conditions do exist, then consumption-based estimates are the easiest method to use.

If, however, program services are in a rapid growth phase, or no consumption information exists, then this method will not provide accurate estimates. It should also be remembered that the issue of drugs from a supply center is not the same as demand for health services at the provider level. There may well have been people who needed drugs but were unable to get them because of shortages. To this extent, consumption records underestimate real demand.

Method

(1) Analysis of historical data -- The past is the place to start in making this type of forecast. The first step is always to graph the data. For this system a facility should have records of monthly distribution of drugs; for the program as a whole there should be monthly summaries of supplies dispensed from clinics.

Another approach is to summarize production and importation records which may be obtained through customs records, import licenses and Ministry of Commerce data. Whichever records are used, a graph of the data will reveal trends and the extent of monthly variation. If you think there is some straight line that fits the data then draw it in. A plexiglass ruler is probably better than linear regression,

because you can more easily use your judgement regarding treatment of spurious data points. This procedure is illustrated in Figure II.B.2.a. Wild data and old data are rejected in "fitting" the trend line.

As a basis for forecasting demand this procedure makes the assumption that the underlying process will continue unchanged throughout the forecast period. This may not be true. It is more valuable to make some estimate of variation. For example, one could estimate a most likely, an optimistic, and a pessimistic value (the so-called MOP values of critical path analysis). These provide an indication of the degree of confidence you have in your estimation procedure, and provide the necessary information for the calculation of safety stocks. For example, if a regional warehouse dispenses 100,000 penicillin tablets during the busiest month of the winter flu season, and only 20,000 tablets during the slowest month of the year, then these figures represent the limits of confidence. An "average" estimate of 60,000 penicillin tablets/month could provide sufficient safety stocks.

Several quantitative, but technically demanding methods of projecting future consumption from past consumption exist (see chapter references). An example of one method is given in Figure II.B.3.

(2) Anticipating program growth -- Health programs grow slowly initially, then there is a rapid expansion phase, and finally a plateau. This gives rise to the well known "logistics" or S-shaped curve, shown in Figure II.B.2.b. This knowledge is important, because it indicates that relying on straight line projections of demand will be inadequate in situations of rapid program growth. In this case, one of the other estimating methods should be used.

Figure II.B.2.

Straight-Line and Typical Program Growth Curves

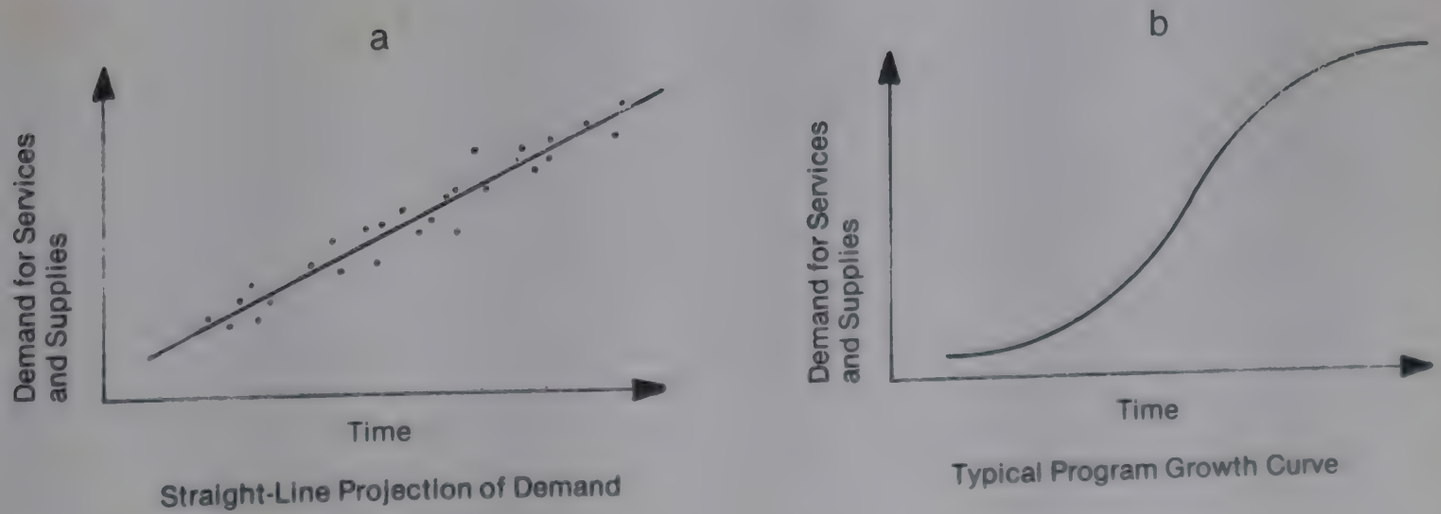


Figure II.B.3.

Forecasting Consumption Using Moving Averages

To eliminate the randomness in a set of demand figures, an average of recently observed values is used in forecasting consumption. This is termed the method of Moving Averages. A set of observed values is taken, their average figured, and that average used to forecast demand for the coming period.

The number of time periods to be included in the moving average should be carefully selected by taking into consideration the types of drugs and their general demand characteristics. Including more observations (larger N) has a smoothing effect on the forecast. Hence, it would be helpful to use a large N when dealing with a stable set of consumption figures and to use a smaller N when figures are seen to fluctuate considerably.

The estimated average monthly consumption of a drug ideally should be available for a period of about one year. Only if past annual consumption figures for individual drugs are available for a sufficiently long period of time, can the method of moving averages be used as described above. If the monthly consumption is too short for analysis, quarterly or yearly projections can be made. In this case the forecast is for one quarter or one year in advance and some correction factor may be needed to account for any seasonal or other trend.

An example has been worked out to illustrate the principle of this method of Moving Averages, based on a moving period of 3 months and 5 months.

Month	Observed Demand (Units)	Forecast With a 3 Month Moving Average (Units)	Forecast With a 5 Month Moving Average (Units)
1	4000	-	-
2	2700	-	-
3	2100	-	-
4	3950	3534	-
5	6200	3516	-
6	3500	4684	4150
7	3100	4550	4050
8	2600	4266	4130
9	4400	3066	3870
10	5540	3366	3960
11	4700	4184	3830
12	-	4880	4068

3. MAINTAINING ADEQUATE DRUG QUANTITIES

Once programs have obtained their initial procurement of drugs and begin providing drugs, it is critically important to maintain adequate quantities. Initial quantities may have under- or over-estimated demand, and good consumption information must be obtained through an effective information system. In addition, some knowledge of the supply pipeline and delivery times are needed. Finally, there are several factors which may reduce the availability of drugs, including failure to reconcile needs and funds, and losses due to damage, spoilage, expiration, and theft.

All of the factors which influence the adequacy of drug supplies are considered in greater detail in subsequent chapters and are described only briefly below.

a. Information System

Adequate information on consumption and the lead time for new shipments are critically important for maintaining adequate quantities. If inventory levels are not followed closely, consumption patterns can be well understated and inadequate amounts of drugs are reordered. Likewise, delays in delivery have the same effect. This is, unfortunately, a major cause of program failure. The initial allotment of drugs allows the health program to aggressively pursue its service targets, but momentum is soon lost if adequate quantities are not maintained. Chapters III.B. and IV.B. describe in detail the procedures and information required to maintain supply.

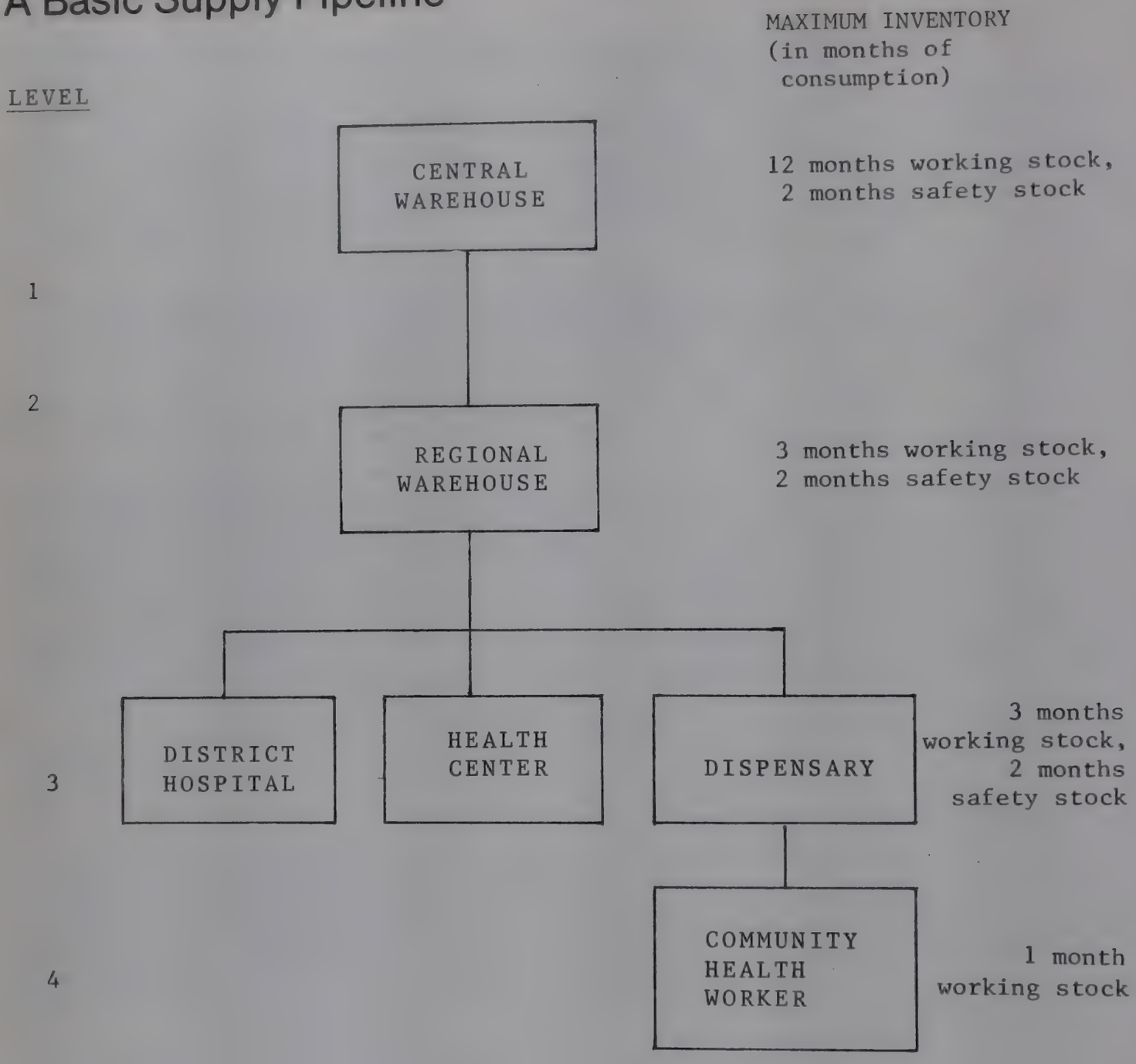
b. Pipeline Considerations

The term "pipeline" refers to the internal levels of the supply system and the number of supply points at each level. The number of levels, the frequency with which supplies are requisitioned and delivered at each level, and the amount of safety stock at each level all influence the amount of drugs needed to fill the pipeline and, hence, the amount which must be procured when a program is started or expanded.

A model of a supply pipeline is presented in Figure II.B.4. This shows that 25 months' worth of stock would be required to completely fill the pipeline if drugs were received once a year at the central level; delivered every three months to the regional warehouses and the district hospitals, health centers, and dispensaries; and supplied on a monthly basis to community health workers; and if two months' safety stock were maintained at each level except at the community level. This may be an over-estimate, since it would be unusual for all levels of the system to be at their maximum stock levels at the same time. Nevertheless, underestimation of the pipeline is a common cause of program failure, particularly where a revolving drug fund has been planned. Country Study III.E.5. (Chapter III.E.) describes in detail pipeline estimation for a drug sales program. Calculation of working stock and safety stock, on which pipeline lengths depend, is discussed in Chapter IV.B.

Figure II.B.4.

A Basic Supply Pipeline



c. Impact of Lead Time

The initial order of drugs should be in large enough quantities to last until the next procurement is made. When all of the steps of the procurement process are added up, it is normal to find that it takes several months to complete all of the paperwork within the bureaucratic components that are involved. In addition, once an order is placed, several more months are usually required for the drugs to arrive in country, clear customs, and arrive at the central warehouse. The waiting period from the time the need for a drug is recognized until it arrives in the country is termed the "lead time".

Lead times vary considerably, but they are usually underestimated -- which leads to unexpected shortages -- and are, in fact, over one year in many cases.

If delivery time can be reduced, this will increase the validity of reorder estimates. For example, if it takes six months for the first year's supply of drugs to arrive, then six months of experience will be available before the next order needs to be replaced, also allowing for a six month delivery time. This may allow sufficient time to generate consumption data and refine initial drug estimates. In addition, shorter lead times reduce the amount of inventory needed as safety stock. Therefore, all efforts should be made to reduce delivery time. This is discussed in detail in Chapter VI.B.

d. Reconciling Needs and Funds

It seems to be a fundamental characteristic of human beings that our needs -- or at least our wants -- almost invariably exceed our resources. Those who work the fields wish to have more seed, better seed, and more fertilizer than they have money for; those who tend the herds wish to have more animals and animals of a better stock than they can afford to buy; and so on. Thus, it is often found with drug supply programs that the perceived needs -- even those determined methodically from information about disease patterns and treatment norms -- outweigh available resources. The possible responses to this imbalance are, unfortunately, sometimes impulsive, short-term, and poorly conceived.

When the perceived needs are greater than the available resources, the imbalance should be dealt with systematically by increasing the availability of funds, by decreasing drug expenditures, or both. Various funding alternatives are discussed in detail in Chapter III.E. and need not be repeated here. Actual drug expenditures can be controlled at several points in the supply system, since drug costs are potentially influenced by drug selection, procurement practices, theft and loss prevention, drug prescribing patterns, and numerous other factors. These are covered elsewhere in this manual, particularly in Chapter VI.B.

The following guidelines may be of value in reconciling needs and funds:

- If cuts in drug purchases are necessary, set rational priorities for these cuts. In some supply programs, when estimated requirements exceed the budget, cuts are made equally across all items -- vaccines and antibiotics are cut as much as cough syrups. Systematic choices should be made to assure that the most needed items are bought first. A method such as the VEN system (vital, essential, non-essential) described in Chapter VI.B. should facilitate this. Adjustments in supply quantities should be made by a pharmacist or physician, rather than by a supply clerk.

- Expenditures should be monitored regularly throughout the fiscal year (budget year). Programs which allow unconstrained ordering of drugs by the procurement unit often find that by the middle of the fiscal year, nearly all of the funds have been exhausted and end-of-

the-year stockouts result. To prevent this, some programs make only one annual purchase (probably not the best idea -- see Chapter IV.B.) or estimate in advance the cost of each major order, making adjustments if the budget is being overspent.

- Review carefully drug and dosage selections. If the selection guidelines presented in the preceding chapter and summarized at the beginning of this chapter are followed, then drug selections should be fairly economical. Nevertheless, further reductions may be possible if the list is thoroughly scrutinized and the guidelines are again applied to remove unnecessary drugs, substitute less costly drugs, and select only the most economical dosage forms.

e. Anticipating Losses

Inevitably, some supplies will be lost in storage or transit due to damage, spoilage, expiration, and theft. Accordingly, a margin of at least 30% above anticipated consumption should be purchased. This margin should be gradually reduced as improved supply management decreases these losses.

SUMMARY

A methodical approach to determining drug quantities is needed when:

- a new supply system is being established,
- an existing system is being reorganized, or
- current drug use is inefficient or irrational.

There are three methods for estimating quantities needed:

Population-based: Survey and/or estimate the prevalence of various conditions in the population and, based on accepted or devised treatment norms, estimate drugs needed to treat the population.

Service-based: Determine the number and types of health providers available and the diseases they will be likely to treat. Based on the amount of services provided and standard treatment norms, quantities are estimated.

Consumption-based: Gather information from commercial sources (where available), private voluntary organizations, or government programs on previous drug utilization.

The determination of order quantities should include consideration of:

(1) the supply "pipeline" -- the number of levels in the supply system, the number of supply points, and the safety stock held at each level,
(2) the lead time -- the waiting period from when a drug is ordered until it arrives,
(3) limited funds which may require cutbacks in order quantities,
(4) potential losses in storage or transit due to damage, spoilage, expiration, and theft.

CHAPTER II.B. REFERENCES

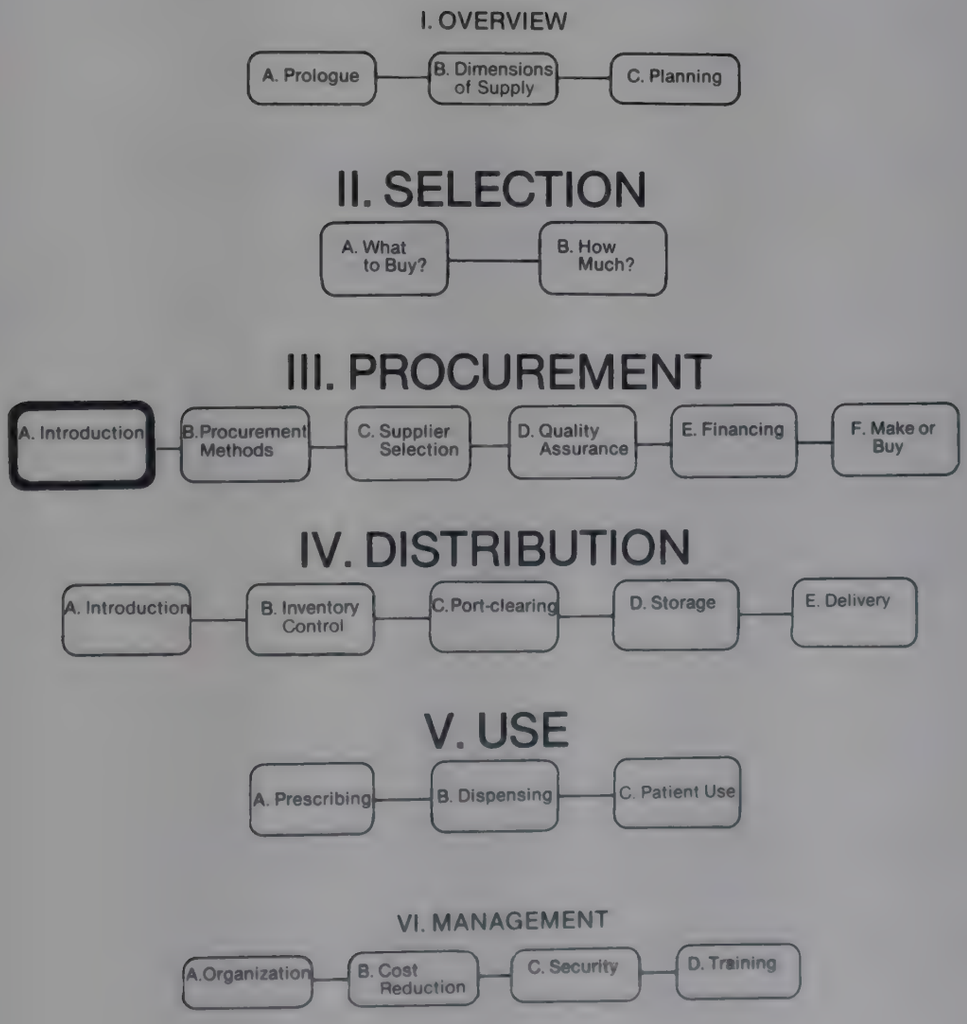
Brown, R.G.: Statistical Forecasting and Inventory Control. New York: McGraw Hill, 1959.

Dias, V.: Introduction to Forecasting and Inventory Control Systems. Colombo, Sri Lanka: State Pharmaceutical Corporation Report 1, National Institute of Management, 1975.

Wheelwright, S.C. and Makridakis, S.: Forecasting Methods for Management. 3rd Edition. New York: John Wiley and Sons, 1980.

Chapter III.A.

Introduction to the Procurement Cycle



		Page
1.	STEPS IN THE PROCUREMENT CYCLE	101
	Review Drug Selections	
	Determine Quantities Needed	
	Reconcile Needs and Funds	
	Choose Procurement Method	
	Locate and Select Supplies	
	Specify Contract Terms	
	Monitor Order Status	
	Receive and Check Drugs	
	Make Payment	
	Distribute Drugs	
	Collect Consumption Information	
2.	CHARACTERISTICS OF A WELL-RUN PROCUREMENT PROCESS	106
3.	COMPONENTS OF THE PROCUREMENT PROCESS	107
	Personnel	
	Procedures	
	Information System	
	Other Components	
4.	RELATIONS WITH DONORS	110
5.	ORGANIZING PROCUREMENT ACTIVITIES	110
SUMMARY		111
REFERENCES		112

Introduction to the Procurement Cycle

Most of the decisions and actions which determine the types of drugs available, the quantities obtained, the prices paid, and the quality of drugs and packaging fall within the procurement cycle. Because of the impact which the procurement process has on these factors and, thereby, on the operation of public health programs, it is essential that procurement activities be performed by trained staff, using sound procedures, working in adequate offices, with reliable inventory and consumption information. Participants in the process must have medical, pharmaceutical, managerial, economic, and often political expertise.

Procurement is defined here as the process of acquiring supplies. The acquisition may be made by purchasing the needed drugs from a private or public supplier for an agreed-upon price, by contracting with agencies such as UNICEF, WHO, or national bilateral aid programs for donation of needed drugs, or by arranging for the manufacture of specific quantities of individual drugs, if government production facilities exist. These three procurement sources -- purchase, donation, and manufacture -- may be used individually or in combination to fill the entire range of drug needs for a public health program.

Although the following chapters on procurement are written primarily with centralized procurement in mind, the principles and procedures necessary for centralized procurement can be readily applied to procurement at any level from a rural aid post to a major national health program. When procurement is done at the local level, the details of the procurement process may be slightly different and the procedures somewhat simplified; however, the basic steps of the procurement cycle (Figure III.A.1) and the basic principles of sound professional procurement should be followed.

Assessment Guide III.A. provides an informal self-assessment of current procurement activities. It is intended to serve as a starting place for anyone wishing to understand and evaluate the procurement activities of an individual health program or procurement office.

1. STEPS IN THE PROCUREMENT CYCLE

In an on-going public health program procurement should be a cyclic process, in which the same sequence of steps is followed each time new supplies of drugs are needed. The major steps in the procurement cycle are summarized in Figure III.A.1. In many areas it may take more than a year to complete one full cycle. Therefore it is essential that a timetable be established for each procurement cycle and that this timetable be adhered to as rigidly as possible.

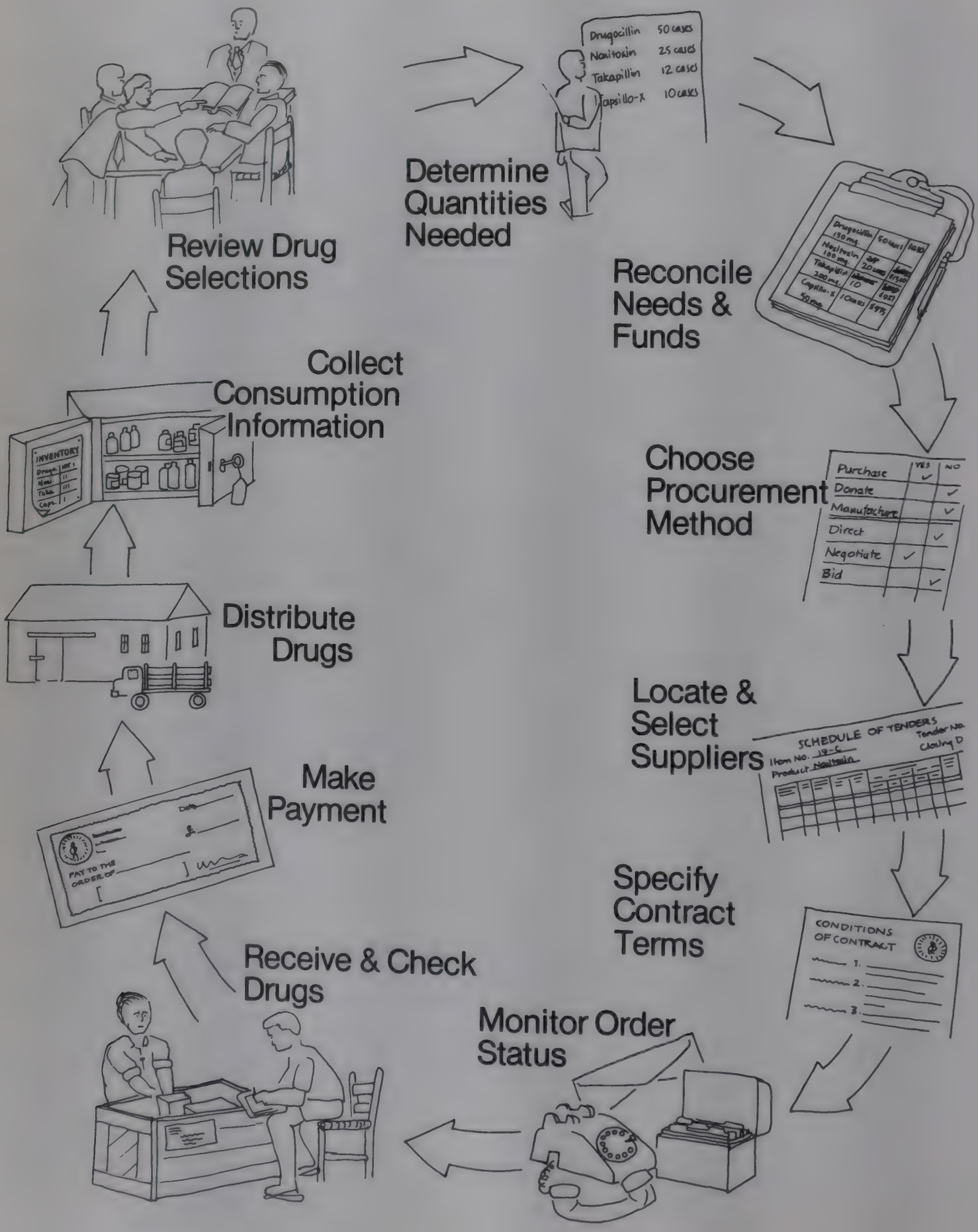
An important concept in procurement is "lead time", the amount of time between the determination of drug needs and the eventual availability of drugs

04700

COMMUNITY HEALTH CELL
LIBRARY
AND
DOCUMENTATION

Figure III.A.1.

The Procurement Cycle



ASSESSMENT GUIDE III.A.

Assessment of Procurement Activities

- How much of how many kinds of pharmaceuticals are procured each year? What proportion of drugs are purchased? Donated? Manufactured by the government? Are all sources of donated drugs known?

- What are the unit prices paid for the drugs? How are these prices determined? Public bid? Closed bid? Supplier quote? How do these prices compare with commercial wholesale and retail prices? How do they compare with prices paid by programs in nearby countries?

- How often are there shortages because drugs do not arrive on time? Is this because orders are placed too late? Suppliers respond slowly? Suppliers fail to deliver on schedule?

- Are the procedures for procuring drugs clearly described somewhere? Is there one procedure for all drugs, or do the procedures vary with the type of drug, the purchase quantity, or the urgency with which the drug is needed?

- Does the procurement process result in all of the drugs for one year arriving at one time -- overloading the warehouses, overworking the staff, and overburdening transportation systems?

- Is there a system for keeping track of which suppliers are reliable? Which suppliers are always late with their deliveries? Which suppliers commonly make mistakes in their shipments? Which suppliers generally use inadequate packaging? Which suppliers make tablets that fall apart before reaching the patient and solutions that stick to the bottom of the bottle?

- Are there procedures for reviewing the drug selections, the order quantities, the technical specifications, and the contract terms? Are there routine procedures for selecting suppliers, monitoring suppliers to assure punctual delivery, and checking deliveries before full payment is made?

- Who are the people responsible for drug selection? Determining order quantities? Choosing the procurement methods and terms? Monitoring orders? Arranging financing? Setting quality standards? What is the training and experience of these people? Are the training and experience sufficient for the jobs they do?

- Where do the activities of the procurement cycle take place? Are these facilities adequate? Is there adequate space and sufficient filing capacity for record-keeping? Is there access to sufficient facilities for printing, copying, or reproducing forms and records?

for use. Inexperienced or untrained procurement officials commonly underestimate the lead time. Underestimates as great as 6 months are not unusual, since actual lead times range from 6 to 24 months. Figure III.A.2. shows a typical procurement cycle timetable.

Although completion of a single procurement cycle often takes a year or more, it is not necessary to finish one procurement cycle before the next one begins. In the example in Figure III.A.2., the complete lead time is 14 months, yet orders are initiated every 6 months. This means that at certain times there will be orders in process for three different procurement cycles. The potential for confusion of orders underlines the need for keeping accurate, complete order records and closely monitoring the process.

With average lead times of 6 to 18 months, the process of estimating future drug requirements becomes even more complex and the need for accurate estimation techniques even greater. Shortages of some items and surpluses of others are inevitable unless the procurement unit is linked to a dependable drug use information system and is adept at forecasting techniques such as those described in the preceding chapter (Chapter II.B.).

The steps in the procurement cycle -- discussed in detail in individual chapters -- are as follows:

(1) Review Drug Selections (Chapter II.A.) -- Efficient drug procurement requires that there be a specific mechanism for determining exactly which items will be needed. At the inception of a program, the process of drug selection may be laborious and time-consuming. Nevertheless, once a basic drug list has been established it is useful to periodically review the list and, based on the most recent field experiences and any new drug information, to make judicious additions and deletions.

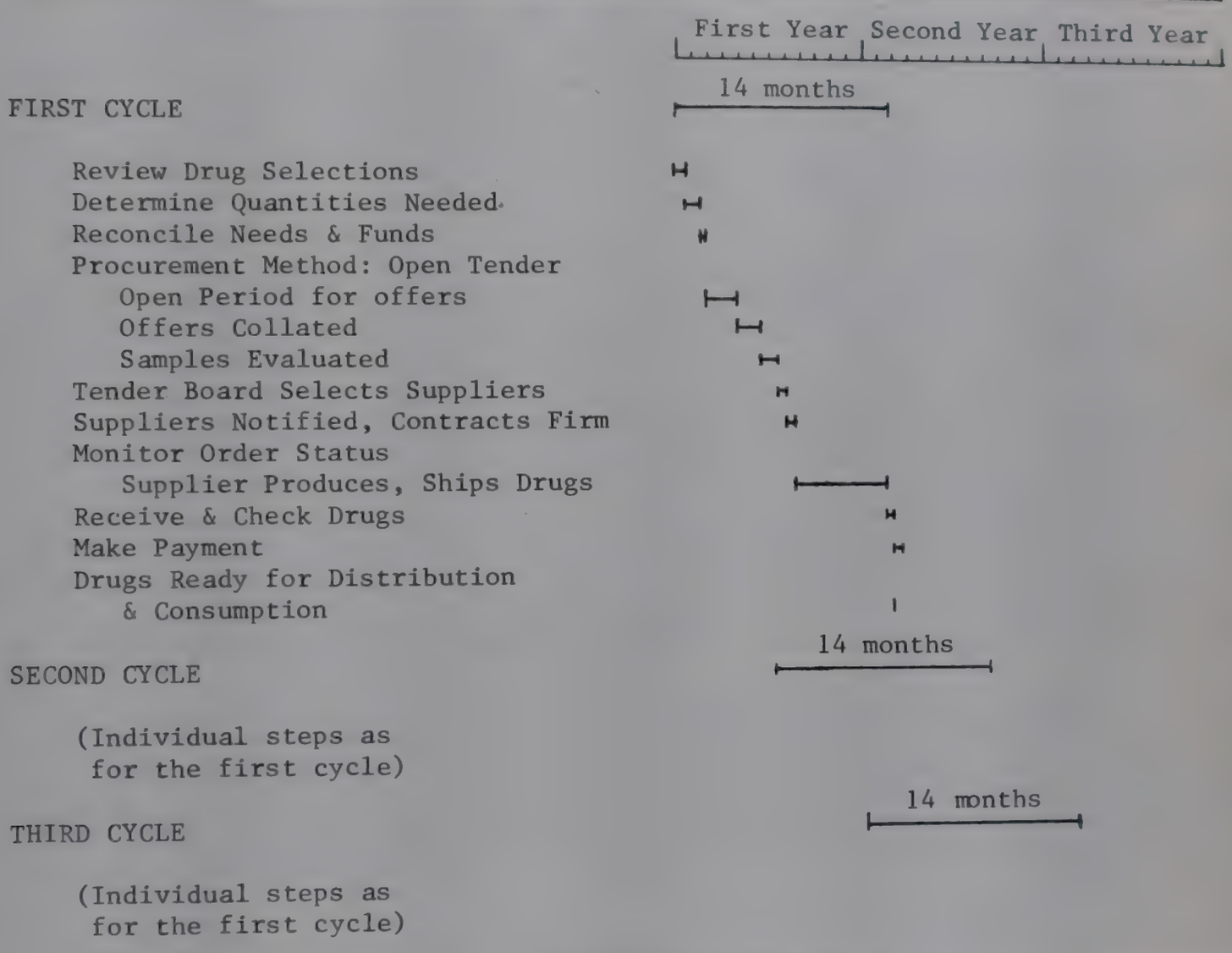
(2) Determine Quantities Needed (Chapters II.B. and IV.B.) -- Once the drug list is etablished or revised, it is necessary to determine how much of each drug is to be acquired. In an established program, accurate consumption information provided by well-kept inventory records is vital for efficient procurement. The distinction between drug needs and drug wants may be difficult. Mechanisms for setting procurement priorities are considered in Chapter VI.D.

(3) Reconcile Needs and Funds (Chapters II.B. and III.E.) -- All too frequently initial estimates of drug needs exceed the amount which can be purchased with available funds. Maximal use of donated supplies may reduce the gap between needs and funds, but any remaining differences must be eliminated by obtaining additional funds or by systematically reducing the number and quantity of drugs.

(4) Choose Procurement Method (Chapter III.B.) -- Once specific drugs and exact quantities are determined (and adjustments are made for expected drug donations and for government manufacture, where it exists), the process of purchasing drugs begins. The choice of the purchasing method (e.g., direct purchase versus open bid) and specific trade terms (e.g., payment schedule) will have important influences on the price, quality of drugs and packaging, and promptness of delivery. The manner in which public bids are publicized will affect the number and types of suppliers who tender an offer.

Figure III.A.2.

Typical Drug Procurement Timetable— Procurement Cycles Overlap



(5) Locate and Select Suppliers (Chapter III.C.) -- Whether an individual supplier is chosen in advance for a direct purchase or a supplier is chosen from a number of bidders, the process of supplier selection is crucial. It requires a knowledge of the sources of pharmaceuticals, an ability to locate potential suppliers, and a means to evaluate supplier reliability.

(6) Specify Contract Terms (Chapter III.B.) -- Supply contracts or other formal statements of the supply terms should indicate the name of the drug, the quantity, the packaging specifications, the quality standards to which the drug must conform, the delivery date, the minimum acceptable shelf-life, the penalty (if any) for failure of the supplier to meet contract obligations, and other technical details. Failure to state supply terms completely and explicitly contributes to disappointing supplier performance.

(7) Monitor Order Status (Chapter III.B.) -- Once an order is placed, the progress of the order must be closely monitored. Delays in the shipment or receipt of drugs should be rapidly identified and the supplier should be contacted immediately. Early detection of overdue orders is essential to prevent shortages.

(8) Receive and Check Drugs (Chapters IV.C. and IV.D.) -- Once drugs arrive they should be placed immediately in a secure storage area. Each shipment must be checked to confirm that the supplier has provided the correct drug, quantity, packaging, shelf-life, and labeling, and has fulfilled any special contract requirements. This step is essential for quality assurance as well as for preventing fraud and other waste.

(9) Make Payment (Chapters III.B. and III.E.) -- Payment for drug shipments may occur in the form of an advanced commitment of funds through a letter of credit, or may follow the actual receipt of the drugs, according to standard commercial terms. If payment is made in advance, a percentage of the price can be withheld as a performance bond. This remaining amount is paid only after the drugs are checked and found to comply fully with the contract requirements. Government dependability in paying for drug supplies is important in maintaining reliable supply sources.

(10) Distribute Drugs (Section IV.) -- The procurement function ends and the distribution function begins when drugs have been accepted from the supplier and placed in the central medical store. But the work of the distribution network will be strongly influenced by the range of drugs, the quantity of drugs, and the quality of drugs and packaging obtained through the procurement function.

(11) Collect Consumption Information (Chapter IV.B.) -- As a routine part of the distribution process, accurate inventory records must be maintained at each level of the distribution network and consumption information must be forwarded to higher levels in the system. In an established health program, reliable drug use information is essential for the review of drug selections and for the efficient and economical procurement of drugs during each successive procurement cycle.

2. CHARACTERISTICS OF A WELL-RUN PROCUREMENT PROCESS

Drug procurement is a professional activity which should be performed by trained staff following carefully established procedures, with accurate drug use information and adequate communication systems, working in suitable offices. The annual cost of operating a procurement office is usually a fraction (less than 5 to 10 percent) of the total amount paid for drugs each year. Attempts at small savings in the day-to-day performance of procurement functions (e.g., through reduced staff, or poorly trained or poorly paid staff) can lead to losses many times greater, if these economies prevent the staff from obtaining available donations or the lowest drug prices possible.

Assessing the effectiveness and efficiency with which the procurement system operates is sometimes difficult. Nevertheless, when well-managed, the procurement process should accomplish the following objectives:

- Acquire needed supplies as inexpensively as possible. In all procurement activities the procurement officers should get the best value for the money.

- Obtain supplies which meet reasonable quality standards for both drugs and packaging.

- Assure prompt and dependable delivery of drugs by careful supplier selection and monitoring of orders.

- Accommodate increased demand during epidemics and other emergencies, while making minimal use of costly purchasing and transportation methods.

- Distribute the workload as evenly as possible throughout the year in order to avoid periods of inactivity alternating with periods of overwork.

- Optimize inventory management through procedures which avoid overstocks (especially of dated products), avert shortages, and minimize the amount of inventory needed to maintain a constant supply for distribution.

3. COMPONENTS OF THE PROCUREMENT PROCESS

Performance of procurement activities requires trained personnel, a suitable organizational structure, well-designed procedures, a functioning information system, and adequate funds, facilities, and equipment. Among these, the personnel, the procedures, and the information system are critical for achieving the objectives of the procurement process.

Personnel -- Too often the performance of procurement activities is left to inadequately trained clerical personnel. Drug procurement is a professional activity. It requires individuals with expertise in inventory control and forecasting techniques, financial planning, international trade, contract writing, pharmaceutical science, and other technical fields. Training and experience in these areas may be lacking in newer programs, and even in some long-standing programs the procurement personnel lack some useful skills. Pharmacists with business training and experience are particularly well-suited to managing drug procurement, since they understand the product so well.

A commitment to efficient procurement requires a commitment to staff development. This manual may play a part in staff development, but formal training programs such as those outlined in Chapter VI.D. are worthy of consideration.

The staffing pattern for a procurement unit will vary with the needs of the individual program. It also depends on whether procurement is a centralized government function, with purchasing for all government agencies being done by one office, or a decentralized function, in which each ministry or each health program does its own procurement.

A typical procurement unit might include the following staff:

- Director of Procurement -- Experienced procurement officer with bachelor level training in business and, preferably, training in pharmacy. Responsible for overseeing all procurement activities and for participating in ministry-level policy discussions concerning drug selection and drug logistics.

- Chief Order Clerk -- Somewhat less experienced individual with formal education in language, mathematics, business, and some science. Responsible for supervising order clerks and assisting the director.

- Order Clerks I, II -- Several individuals with 8-12 years of formal education and with skills in language and mathematics. Handle much of the paperwork involved in preparing public tender announcements, corresponding with suppliers, collating offers to prepare a schedule of tenders, and monitoring order status.

- Typists -- Bilingual capability useful, as well as familiarity with common trade language(s), to handle correspondence with suppliers and other foreign parties.

Procedures -- In the following five chapters we discuss specific alternatives for handling most of the decisions and activities involved in drug procurement. Regardless of which approach is taken, procurement procedures must be clearly stated and followed as closely as possible. But procedures should also be allowed to evolve. They should be modified whenever experience or new information indicates that an alternative procedure would be better.

For example, a growing procurement program might make all of its tenders open to any supplier. This would encourage the largest number of participants in the bidding process. Later, after the program has located enough potential suppliers and collected information on supplier reliability, the procedure might be changed to specify that bids will be accepted from only a limited number of registered suppliers.

Efficient procurement relies on the initial establishment of sound procedures and subsequent modifications of these procedures to reflect new insights.

Information System -- A shortage of oral penicillin in the face of a large excess of injectable aminophylline and similar mismatches are commonplace in public drug programs. Many factors contribute to such mismatches, not the least of which is inadequate funding. Nevertheless, the absence of a functioning information system is a familiar deficiency. When essential drug needs can be accurately anticipated in advance, the economies of bulk purchasing are maximized and the expense of emergency shipments minimized. However, accurate estimates of future drug needs can be made only if inventory records are conscientiously kept, consumption reports regularly prepared, and changes in drug needs foreseen.

Thus, an important function of the individuals involved in drug procurement is promoting the development and maintenance of information systems for drug use and public health.

Figure III.A.3.

Government Participants in Centralized Procurement—A Sample Staffing Pattern

Government Unit	Staff (Committee Members)	Major Responsibilities
Procurement Unit	• Director of Procurement • Chief Order Clerk • Order Clerks I,II • Typists (national and trade languages)	• Oversee and Coordinate All Procurement Activities • Determine Order Quantities Based on Inventory Control and Planning Unit Reports • Determine Procurement Methods • Publicize Tenders and Locate Suppliers • Prepare Schedule of Tenders for Tender Board • Maintain Supplier and Product Files to Assist in Supplier Selection • Specify Contract Terms • Monitor Order Status
Therapeutics (Formulary) Committee	• Ministry Representatives • Physicians (General Practice, Internal Medicine, Infectious Disease, Surgery, etc.) • Pharmacists • Medical Educators • Health Service and Program Directors	• Establish the Formulary or Basic Drug List at the Inception of the Program • Review and Revise Drug Selections Periodically • Study and Act Upon Requests for Additions to or Deletions from the Drug List • Assist in Reconciling Needs and Funds
Tender Board	Similar to Therapeutics Committee, sometimes with representation from Finance, Foreign Affairs, Commerce, and/or other Ministries	• Study the Tender Offers and Select Suppliers Based on Cost, Quality, Past Performance • Adjust Order Quantities when Unit Costs Prohibitively High
Planning Unit	• Director of Planning • Planning Staff	• Participate in Drug Selections • Establish Health Service Targets • Prepare Predictions of Drug Requirements for New or Expanding Programs
Finance Unit	• Director of Finance • Chief Supply Accountant • Supply Accountants I,II	• Determine Operating Budget and Drug Budget • Assist in Reconciling Needs and Funds • Determine Prices and Account for Funds in Drug Sales Programs • Provide Accounting Reports to Donor Agencies • Arrange Payment of Suppliers
Import Unit	• Import Manager • Customs Clerk • Insurance Clerk • Drivers, Laborers	• Receive Import Documents • Identify the Arrival of Shipments in Port • Monitor and Expedite Port-Clearing Activities • File and Process Insurance Claims
Inventory Control Unit	• Director of Inventory Control • Other Staff (described in Section IV)	• Provide Consumption Reports to Procurement Unit • File Stock Replenishment Requests with Procurement Unit (based on Stock Levels and Reorder Intervals) • Other Inventory Control Activities described in Chapter IV.B.
Medical Stores	• Director of Medical Stores • Other Staff (described in Section IV)	• Inspect All Shipments for Damage, Loss, Short-Packing • Distribution Activities described in Section IV

Other Components -- In addition to personnel, procedures, and an information system, procurement activities require adequate funds, facilities, equipment, and organizational structure. If procurement staff is not obtaining low prices, prompt delivery, and high quality in its work, then it is imperative that the adequacy of all of the components of the procurement process be assessed.

4. RELATIONS WITH DONORS

For some programs, especially new ones, a major source of drugs or funds for the purchase of drugs is donations from international agencies, bilateral aid programs, and charitable groups. Such contributions are needed and welcomed additions to any program's resources. But these contributions should not be exempted from routine supply management activities.

Uncertain delivery times, incomplete import documents, foreign-language labels with unknown brand names, odd package sizes, short shelf-lives, and other difficulties sometimes encountered with donated supplies consume precious staff time and may render some donations useless. To minimize such difficulties, several actions can be taken by the government officials charged with procurement.

First, it should not be assumed that donor agencies or their supply sources are aware of specific supply requirements. Although there may not be a formal contract established, a letter can serve to inform donors of specific supply requirements with regard to packaging, labeling, or shelf-life, for example.

Next, if donated items come with certain restrictions (e.g., non-hospital use only), these restrictions need to be recognized in advance so that necessary arrangements can be made for fulfilling needs not supplied by the donors.

Finally, when shipments of donated supplies are expected, the status of these shipments should be monitored in much the same way that purchases from commercial suppliers are monitored (see Chapter III.B.).

5. ORGANIZING PROCUREMENT ACTIVITIES

Figure III.A.3. depicts one way in which the activities in the procurement cycle can be organized and assigned to individual units. The organizational structure in Figure III.A.3. assumes the presence of several government committees as well as separate functional units for planning, procurement, importation, inventory control, and medical stores. Whether the functions are combined under a single supply director or, as in some countries, separated under several different ministries, the basic sequence of the procurement cycle should proceed in a coordinated way. Inventory control, importation, and medical stores are considered in Section IV., Distribution.

SUMMARY

Procurement is defined as the process of acquiring supplies. The three procurement sources are purchase, donation, and manufacture.

Most of the important decisions and actions which determine the types of drugs available, the quantities obtained, the prices paid, and the quality of drugs and packaging fall within the procurement cycle.

Procurement is a cyclic process which requires a sequence of steps, the timetable for which should be clearly specified and closely followed. Steps in the cycle are:

(1) Review Drug Selections
(2) Determine Quantities Needed
(3) Reconcile Needs and Funds
(4) Choose Procurement Method
(5) Select Suppliers
(6) Specify Contract Terms
(7) Monitor Order Status
(8) Receive and Check Drugs
(9) Make Payment
(10) Distribute Drugs
(11) Collect Consumption Information.

The objectives of a well-managed procurement system are to:

- acquire needed supplies as inexpensively as possible;
- obtain supplies of high quality;
- assure prompt, dependable delivery;
- distribute the procurement workload to avoid periods of idleness and overwork;
- optimize inventory management through wise procurement procedures.

The structural components necessary for procurement include trained personnel, well-designed procedures, a functioning information system, a suitable organizational structure, and adequate funds, facilities, and equipment.

Although donations are welcomed additions to program resources, they should not be exempted from routine supply management activities. Procurement officials should:

- inform donors of supply requirements in regard to packaging, labeling, shelf-life;
- anticipate donations, to fulfill unmet needs through other means;
- monitor shipments of donated supplies according to routine procedures.

CHAPTER III.A. REFERENCES

Ammer, D.S.: Purchasing and Materials Management for Health Care Institutions. Lexington, MA: D.C. Heath and Co., 1975.

Bailey, P.J.H.: Purchasing and Supply Management, 2nd Edition. New York: Chapman and Hall, 1969.

Combs, P.H.: Handbook of International Purchasing, 2nd Edition. Boston: Cahners Publishing Co., Inc., 1976.

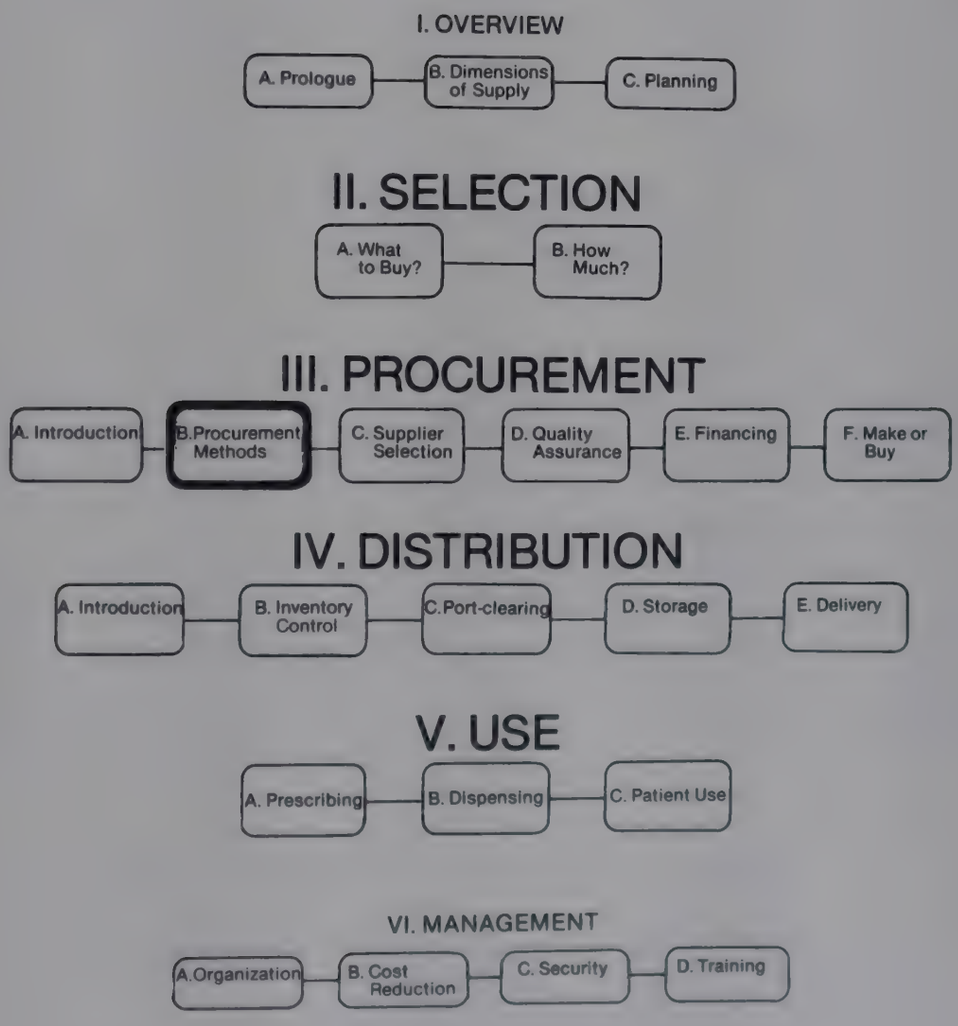
UNIDO: A Guide to Industrial Purchasing. New York: United Nations Industrial Development Orgnization, 1972.

United Nations: Supply Management: Towards Better Use of Equipment and Material Resources in Developing Countries. New York: United Nations Department of Economic and Social Affairs, ST/ESA/SER.E/16, 1978.

Westring, G.: International Procurement: A Training Manual. New York: United Nations Institute for Training and Research, 1977.

Chapter III.B.

How to Buy: Procurement Methods and Terms



	Page
1. PURCHASING METHODS	118
a. Open Tender	118
b. Restricted Tender	122
c. Negotiated Procurement	123
d. Direct Procurement	123
e. Choosing Procurement Methods	124
2. CONTRACT TERMS	128
a. Trade Terms	128
b. Price and Currency	130
c. Payment Terms	131
d. Quality Standards	132
e. Nomenclature and Labeling	133
f. Product Specifications	133
g. Financial Guarantees	133
h. Delivery Date	134
i. Patent Provisions	134
j. Packaging	135
k. Expiry Date	135
l. Unique Identifiers	138
3. MONITORING ORDER STATUS	138
SUMMARY	141
REFERENCES	142
APPENDICES	
III.B.1. Summary of Internationally Recognized Trade Terms	143
III.B.2. Standard Letters to Suppliers Regarding Order Status	144

How to Buy: Procurement Methods and Terms

The primary function of the chief procurement officer is to obtain the needed items, at the right time, in the correct quantities, and at the most favorable prices possible. When a requisition has been initiated by the inventory control unit, it is the responsibility of the procurement unit to systematically seek out suppliers, select a reliable supplier, arrange an attractive price, and secure a firm supply contract.

The three important elements of the procurement process which will be discussed in this chapter are:

(1) Method -- Drugs can be purchased directly from suppliers at a pre-established list price, directly from an individual supplier after negotiations of more favorable terms, through an open or unrestricted bid (tender), or through a closed or restricted bid (tender). The choice of method has significant effects on price and on the time required to arrange a contract.

(2) Contract Terms -- The supply contract establishes expectations regarding payment, quality standards, product specifications, delivery dates, and other supplier responsibilities. Careful specification and close enforcement of contract terms contribute greatly to procurement efficiency.

(3) Order Status -- After specific terms have been agreed upon with individual suppliers, the procurement unit continues to follow the progress of an order through communication with the supplier and, if necessary, the shippers, until drugs have been received at the port or warehouse.

The timing of purchasing activities should follow an established pattern. Purchases can be made annually, every two to six months, or almost continuously, with orders for a small number of items being placed weekly. The procurement pattern is closely linked to the inventory control system; therefore, topics concerned with the frequency of procurement or the quantities purchased are covered separately in Chapter IV.B.

Procurement Costs

The cost of purchasing a drug has two obvious components, the price paid to the supplier and any intermediaries and the cost of operating the procurement unit. Both of these costs are "visible costs" and normally vary considerably with different purchasing methods. In selecting procurement methods and patterns, procurement officers need to consider the effect of their decisions on both the cost of the drugs and the cost of performing procurement functions.

But too often purchasing managers consider only these visible costs. There are, in addition, a number of costs which are hidden in the supplier's

ASSESSMENT GUIDE III.B.
Purchasing Activities

- What type of purchasing methods are used? Direct procurement? Negotiated procurement? Restricted tender? Open tender? Other methods?
- Who determines the purchasing methods? Are the methods based on law? Government policy? Ministry policy? Habit?
- Who is responsible for selecting suppliers? On what basis are the suppliers selected in processing open and restricted tender bids? Is a merit rating system used for evaluating supplier performance?
- Have the persons engaged in purchasing been provided with training in this field?
- What contract terms are suppliers expected to adhere to? Do these terms provide sufficient protection from common difficulties such as late deliveries, inadequate drug labeling, short shelf-lives, and poor quality?
- When supply contracts are prepared, are the trade terms, payment terms, and clauses concerning the currency of payment favorable to the supply program?
- Do suppliers frequently refuse to supply an item for which they have won the contract, or do they default on an order? Are any financial guarantees required when bids are submitted? When contracts are awarded?
- Are significant quantities of drugs discarded because drug quality or packaging standards were not established in the contract and enforced?
- Is the purchasing department expected to purchase drugs within a specific period of time? For example, within a single fiscal year?
- Is there any systematic method of evaluating the status of outstanding orders? Is there a system of providing information to other units, such as inventory control, wharf, and distribution, regarding the status of outstanding orders?

past and future performance. The hidden costs, which can significantly increase the ultimate cost of purchasing a product, usually result from the poor quality of drugs supplied and failure to meet delivery terms. Specific hidden costs include:

- Panic buying or air-freighting at higher cost, whenever a critical drug is shipped late or the supplier completely defaults on an order.

- Replacement costs when goods are lost or discarded because of poor packaging, improper shipping conditions, rapid spoilage, or short shelf-lives.

- Storage, port charges, and administrative expenses incurred when proper documentation is not included.

- Transportation costs when goods are delivered to the wrong port.

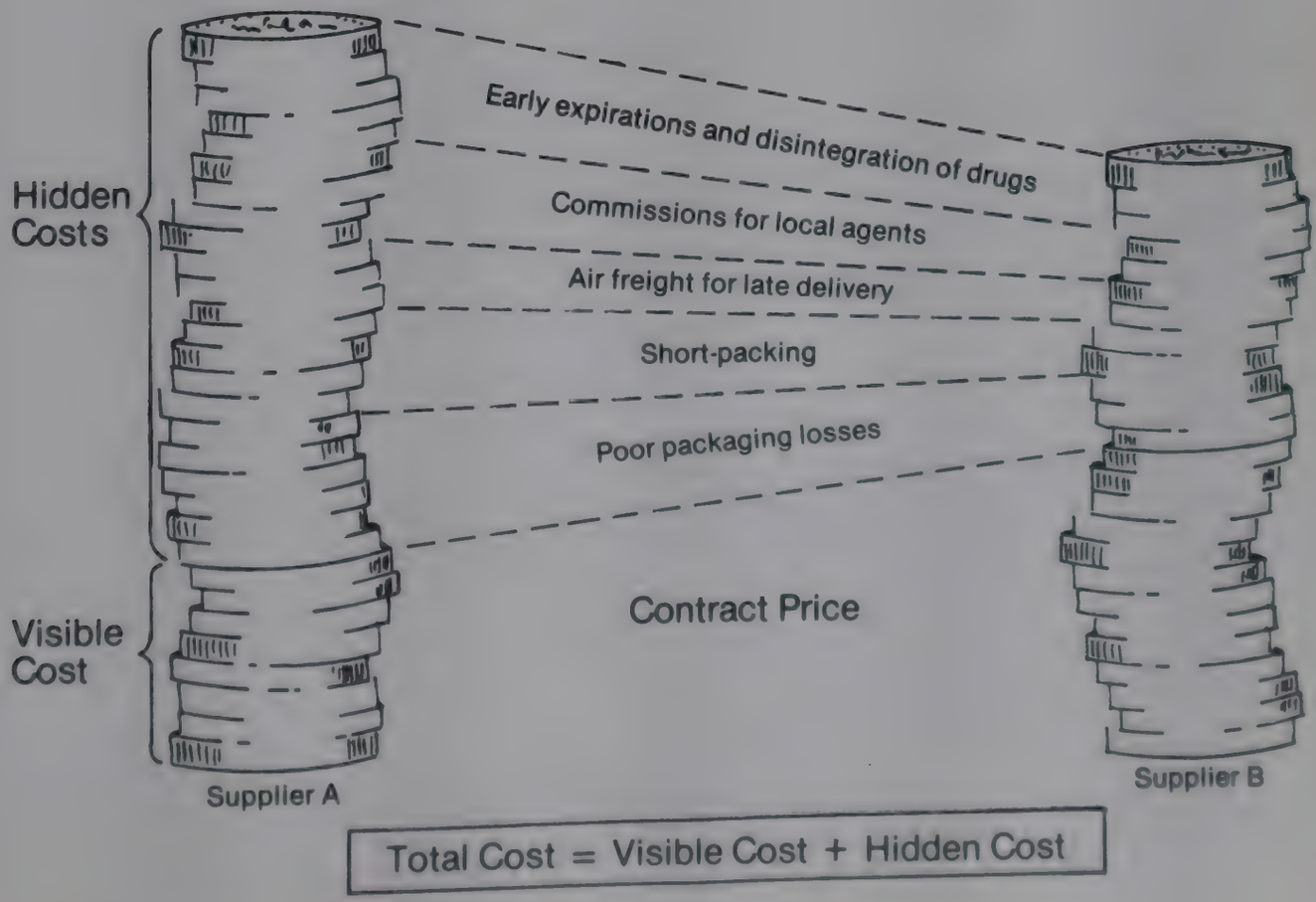
- Health and economic costs of stockouts resulting from delay or default on delivery.

- Higher drug costs when late or damaged shipments require medical workers to use more expensive alternative treatments.

- Replacement costs for short-packings, diluted liquid medications, wrong dosage forms, etc.

The potential impact of hidden costs on the total cost is illustrated in Figure III.B.1. In this example, Supplier A has quoted a lower price (visible

Figure III.B.1.
Impact of Hidden Costs on Total Cost



cost), but losses and additional expenses resulting from Supplier A's poor performance ultimately raise the total cost above that for Supplier B. A large number of suppliers with varying technical and commercial background may tender for particular orders and their quoted prices will vary considerably; the procurement unit must not be guided only by the visible costs, but must consider all hidden costs as well. The presence or absence of certain contract terms may influence hidden costs. The use of a merit rating system to monitor supplier performance may expose them, and thus greatly assist the purchasing function (see Figure III.C.4. in Chapter III.C.).

Procurement Staff

Since drug purchases consume a very large proportion of the total budget of a health ministry in a developing country, purchasing is an important function, and should be carried out by experienced and competent staff.

1. PURCHASING METHODS

For the purchasing department to carry out its functions effectively, it is necessary to select the most appropriate purchasing method for each drug. The four purchasing methods available to a public supply program are:

- Open tender (unrestricted bid)
- Restricted tender (closed bid)
- Negotiated procurement
- Direct procurement

Details regarding these four methods, in terms of their operation, advantages, disadvantages, and conditions favoring their use are given below. A brief description of each method and comparison of their characteristics appears in Figure III.B.2.

a. Open Tender

Open tendering is a formal procedure by which quotations for the supply of a drug under its medical (generic) name are invited from any manufacturer or his representative on a worldwide basis, subject to the terms and conditions specified in the tender invitation.

Conducting an Open Tender

The process of open tendering generally follows a specific timetable, an example of which is given in Figure III.B.3. Once specific drug needs are determined and the technical specifications (medical name, dosage form, package size, etc.) have been prepared, the tender is publicly announced in a call for

Figure III.B.2.

Comparison of Purchasing Methods

Purchasing Method	Brief Description	Effect on Price	Delivery Times	Workload on the Procurement Unit	Need for a Merit Rating of Suppliers	Conditions Favoring Use
OPEN TENDER	Bids are accepted from all interested suppliers.	Very Favorable	Long	Very high	Very High	• Many reputable suppliers are available • May be necessary at beginning of program to open supply channels
RESTRICTED TENDER	Suppliers bid against each other for the contract, but participation of suppliers is limited to those who have registered with the government or who have met established prerequisites.	Favorable	Moderate	Moderate	Moderate	• Where only a few reputable suppliers are available • Products where bioequivalence, sterility, precise formulation is important • Large volume, standard items for which all reliable suppliers are known
NEGOTIATED PROCUREMENT	The buyer approaches a small number of selected potential suppliers and bargains with them for specific price or service arrangements.	Moderately Favorable	Short	High initially, later low	Only initially	• Bulk buying of single-source drugs • Special terms or specifications are required by the buyer
DIRECT PROCUREMENT	Purchase is made directly from a single supplier at his quoted price.	Unfavorable	Very Short	Very Low	No Need	• Low price, small volume items • Emergency items where negotiation not possible • Items from international nonprofit groups (e.g., UNICEF, ECHO, IDA)

Figure III.B.3.

Procurement Timetable for an Open Tender

Number of Weeks	Activity
WEEK 0	Procurement Cycle begins.
	Consumption records reviewed and procurement requirements determined (4 weeks).
WEEK 4	Call for Offers announced.
	Open period for suppliers to submit offers (6 weeks).
WEEK 10	Closing date. All bids due.
	Offers are collated and, where necessary, samples are evaluated (8 weeks).
WEEK 18	Tender board selects suppliers for each product (1 week).
WEEK 19	Letters of offer sent to suppliers, bank guarantees obtained (4 weeks).
WEEK 23	All contracts signed.
	Production and shipment by supplier (20 weeks).
	Drug deliveries begin.
WEEK 43	Drugs received and checked (1 week).
WEEK 44	Drugs ready for distribution.

offers. This announcement may be in the form of local or international publication of all drug requirements with detailed technical specifications, or it may simply be a short notice which requires potential suppliers to write to the procurement unit for the detailed description of drug requirements (see Chapter III.C.).

The latter method saves publication costs on the initial announcement and has the added advantage that suppliers requesting further information can be provided with standard forms on which to submit their bids. Use of such forms can greatly speed and simplify the process of preparing bid comparisons ("Schedule of Tenders", see Figure III.C.6.).

The Call for Offers, also known as an "invitation to quote" or "invitation to tender" is designed to suit individual program needs. The following information should generally be included in the form used:

- Complete product specifications, including any special packaging requirements;
- Realistic delivery date;
- Listing of or reference to the contract terms to which the supplier will be expected to adhere;
- Closing date for receipt of offers by the Procurement Unit;
- Request for the supplier to suggest suitable cost-saving alternatives (well-established, reliable suppliers can be of great assistance in this regard).

The length of the open period (time between the call for offers and the closing date) should be specified in the procurement regulations and varies from country to country between four and eight weeks. A longer open period lengthens the lead time for obtaining needed drugs. On the other hand, it increases the number of offers received. Obviously, if a program is having difficulty attracting enough bidders, a longer open period may be beneficial.

To avoid price manipulations or accusations of price manipulations, the procurement unit must adhere strictly to the closing date. On this date all bids are publicly opened and posted. The procurement unit staff then prepares a Schedule of Tenders to allow side-by-side comparison of the offers by the staff and the tender board. The Schedule of Tenders should include only those suppliers who have satisfactorily met the basic requirements related to the drug description, strength, pack size, delivery date, etc. Prices must be converted to a common currency and adjustments made for differences in trade terms (e.g., adding freight costs to those bids which do not include freight expenses).

After the Schedule of Tenders is prepared, the selection of specific suppliers proceeds as described in the next chapter (Chapter III.C., section 4.) and supply contracts are awarded. When the supplier is selected, it is useful to note the supplier's name and the names of the next two preferences on the Schedule of Tenders, thus avoiding the need for the tender board to meet again if the supplier to whom the award was originally made cannot fulfill the order.

Some countries allow or require an appeal period in which rejected suppliers may request reconsideration by the tender board. The ultimate effect of an appeal period on drug prices and quality is not known, but it certainly can slow the procurement process. Therefore, if there is an appeal period, it should probably be limited to a few days.

Comment

The process of open tendering offers the possibility of significantly lower prices and is feasible if there is a sufficiently large number of reliable manufacturers available. If the number of potential suppliers for each drug is small, this method would not be economical in terms of staff time. Since the amount of staff effort required to operate an open tender is great, the drugs which are bought through open tendering should be carefully selected.

A second problem faced with open tendering is that of assessing the technical and commerical capabilities of individual suppliers. Supplier selection cannot be determined only by price. Methods of evaluating new suppliers and of monitoring the performance of current suppliers are considered in the following chapter. Although open tendering may achieve the lowest prices, it carries the greatest burden in terms of supplier selection and quality assurance.

b. Restricted Tender

In a restricted tender -- also termed a closed bid or selective tender -- a limited number of suppliers are allowed to submit their quotations for the supply of a drug under its medical (generic) name. Normally the number of suppliers is limited to about ten.

It is not worthwhile to call worldwide tenders for certain drugs due to the limited number of manufacturers producing them. For other drugs, quality is of such importance that only a limited number of well-proven suppliers would be considered. It takes time to develop a large enough list of reliable drug suppliers to purchase by this method on a regular basis.

Use of restricted tenders is dependent upon a supplier registration system (see Chapter III.C. and Appendix III.C.4.) or a system of established supplier prerequisites. Once prepared, lists of eligible suppliers need to be approved by the tender board and continually reviewed and updated.

With restricted tenders, the procurement office sends a "Call for Tenders" or "Call for Offers" to approved suppliers and requests offers from these suppliers. Requests are often limited to those items which the individual supplier is known to provide in bulk quantities for public health programs. Suppliers are given a deadline by which they must respond. Offers are then compared as they would be in an open tender (see Chapter III.C.).

After several years of open tendering during which potential suppliers are identified and their reliability is tested, some programs find it advantageous to change to exclusively restricted tendering. When suppliers are

well-known, restricted tendering markedly expedites the entire procurement process and, with five to ten suppliers invited to bid on each individual item, drug prices may be the same as those obtainable through open tenders. Restricted tenders can reduce the lead time by two months or more, the work of processing orders is reduced, and the complexity of calling for quotations is lessened.

In instances where a drug is not normally purchased by this method, it can be used where delivery is urgently required. In such a situation a few reliable suppliers are picked from experience with recent open tenders.

c. Negotiated Procurement

In negotiated procurement, the buyer approaches a small number of selected potential buyers and bargains with them directly to achieve specific price or service arrangements. Although the negotiation process is usually based on some form of competition among suppliers, it can involve negotiation with only one firm.

Negotiated procurement is sometimes used for long-term supply contracts. When entering into such contracts, a great deal of care should be exercised in drawing up the terms and conditions governing the contract. For example, it may be difficult to make accurate forecasts regarding drug requirements; this is especially so in instances where long-term forecasts are involved. Therefore, introducing a certain degree of flexibility to the question of order quantities in the form of a minimum and a maximum would certainly help.

This method of purchasing not only benefits the buyer, but the manufacturers too can profit by it. For example, it helps the manufacturer to plan and optimize his raw materials purchases and production schedules. Some portion of this benefit is normally passed on to the buyer in price breaks. However, much depends on the bargaining powers and skills shown by those negotiating on behalf of the buyer.

In addition to obtaining a lower price, the lead time for delivery under this method is often less as it avoids many formalities such as calling for quotations and comparing suppliers. In spite of its logical attractions, negotiation may not always be an option, since administrative and financial regulations may not permit government programs to enter into contracts which are valid for more than a year, or to enter into such negotiations with suppliers. Nevertheless, whenever health care providers require drugs which are available from only one source, it is worth attempting to negotiate a price which is more favorable than the standard retail or wholesale price.

d. Direct Procurement

The simplest method of procurement is direct purchase from a single supplier at his quoted price without previously requesting offers from other potential suppliers. For single-source drugs (generally those under patent for which no licensing agreements exist to allow other firms to manufacture the drug), the buyer usually has no choice but to adopt this method. In such

monopoly situations, there is little the buyer can do to otain a more favorable price, except to enter into negotiation with the supplier.

Although direct procurement usually involves a minimum of time and effort, prices are generally much higher and, therefore, this method should be reserved for single-source drugs, low-price and small-volume items, and emergency purchases when time does not allow for negotiation with potential suppliers.

When drugs are purchased through an international procurement service, it is generally a direct purchase from the viewpoint of the public procurement unit, since the price is established by the procurement service.

e. Choosing Procurement Methods

In many government programs the procurement methods are mandated by law or by government regulations, in which case the preceding discussion will serve only to help procurement staff to understand the system that they must use. When the system is not so rigid, there exists the possibility of altering existing practices to better serve the procurement function. Country Study III.B.1. describes the purchasing patterns followed by several public drug supply programs.

Figure III.B.4. summarizes the flow of procurement decisions involved in determining first whether drugs will be purchased, and, if so, the method by which they will be purchased. It is important to recognize that not all drugs need to be purchased by the same method, nor must a drug which is purchased by negotiation on one occasion be purchased the same way on future occasions. The choice of procurement method should aim at achieving the following objectives:

(1) Obtain the lowest possible purchase price.

(2) Assure supplier reliability, both in terms of quality and service.

(3) Minimize the opportunity for illicit influences on procurement decisions.

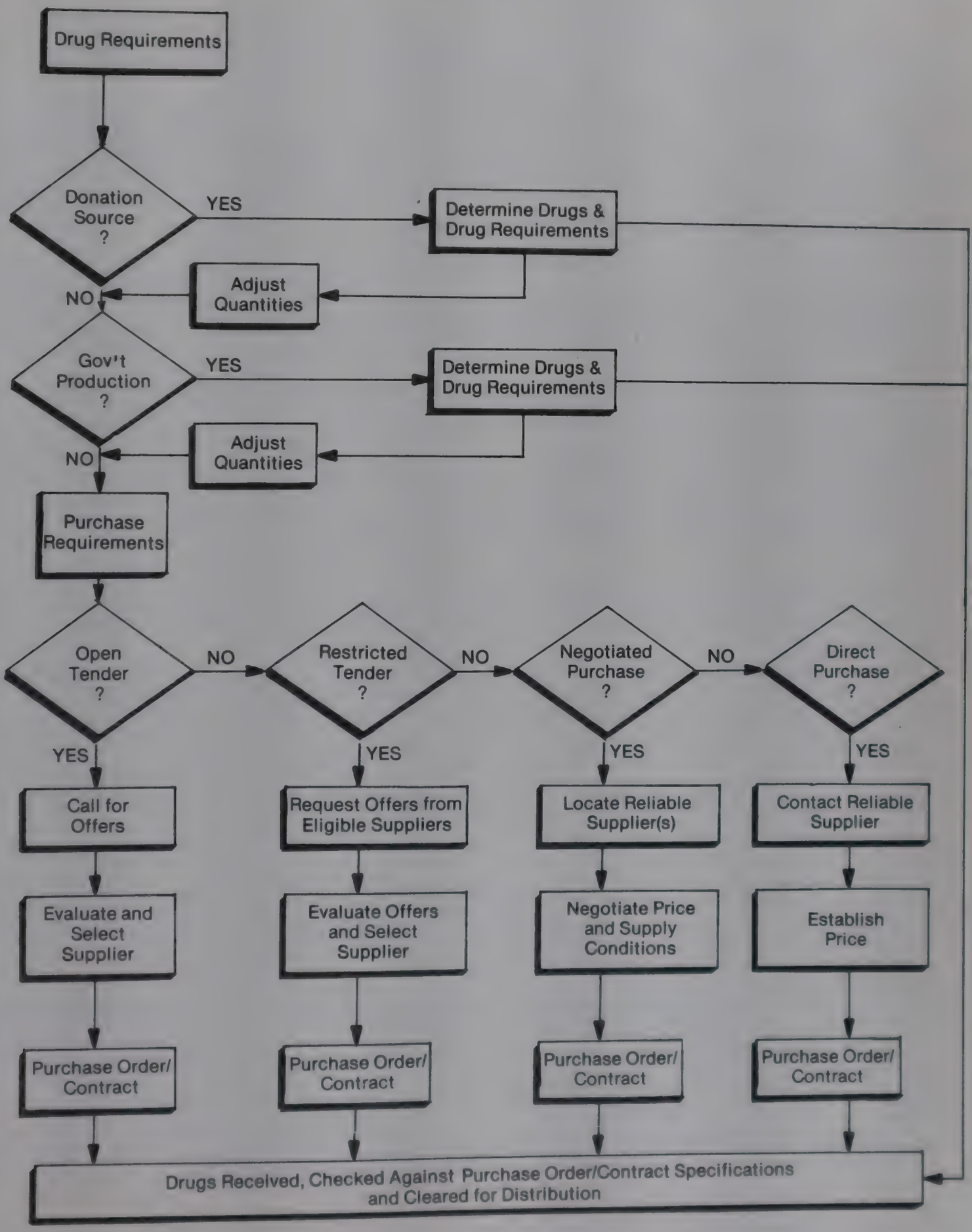
(4) Achieve the above objectives with the least possible professional and clerical staff time and within the shortest possible lead time.

Some of these objectives are obviously in conflict with others and there is no simple way to determine when the overall balance of factors favors one procurement method and when it favors another. The comparison of purchasing methods in Figure III.B.2. should help in making such decisions.

The use of specific monetary cut-off points for direct, negotiated, and tender purchases is useful (see Country Study III.B.1.), provided that the cut-off points are reasonable in the context of the international drug market and the structure of the country's drug needs. More specific, but somewhat technical, guidelines for picking procurement methods are discussed in Chapter VI.B. on cost-reducing strategies.

Figure III.B.4.

Flow of Procurement Decisions



Country Study III.B.1.

Purchasing Patterns of Selected Countries

Honduras -- The Ministry of Health has two categories for pharmaceutical purchases. Eighty percent of available funds are reserved for purchases made at the central level. The remaining 20% is divided up among the eight health regions and national hospitals. The directors of these organizations use the funds at their own discretion to respond to immediate needs.

The Ministry makes one major pharmaceutical purchase annually. The central warehouse maintains a continous inventory of its own stock using stock record cards. Information on stock levels at regional and subregional facilities is not usually available. The Directorate of Administration determines the types and quantities of supplies required and the Division of Procurement prepares the request. The request is then forwarded to the Proveduria Nacional or the government's procurement agency. National purchases are made directly for orders less than U.S.$5000 and by open or closed bid for orders over U.S.$5000. Purchase by regions and national hospitals are normally done directly.

The Ministry is legally obligated to make its annual purchase through the Proveduria. Two commonly heard complaints are that the lead time for delivery is too long, often exceeding a year, and that the Proveduri does not purchase according to the specifications requested. The slow service is especially disruptive because, once the Ministry obligates its funds for pharmaceuticals, this money is beyond reach. When stocks run low special budgetary arrangements have to be made for emergency purchases. This inevitably has a negative effect on program plans.

Tanzania -- In the past the majority of purchasing was done through the British Crown Agents. Recently, an increasing proportion has been done through The Ministry of Health's Central Medical Stores (CMS), using a combination of open tenders, direct purchases, and international purchasing agents. Multi-source, high consumption drugs are purchased through internationally publicized open tenders. About one-third of the drugs are purchased directly from suppliers at established list prices, the principal supplier being the government affiliated National Pharmaceutical Company (NAPCO), which is also the chief importer of commercially sold drugs. Single-source drugs, multi-source drugs whose availability is limited for other reasons, and low-consumption drugs are purchased through international purchasing agents such as the British Crown Agents and the International Trading Agency for Tanzania in Holland.

Tendered items are generally purchased once a year, with arrangements made for 2 to 4 divided deliveries. The remainder of the drugs are purchased twice a year, generally once early in the year with an adjusting purchase later in the year. The local purchases from NAPCO occur during emergencies, when the CMS has run out of an essential item, or when foreign exchange is limited and the government wishes to buy drugs which are already in the country.

Malaysia -- A perpetual inventory is maintained on a card file, which is updated daily with the issuing an receiving forms. Under a system of scheduling indenting, a different inventory category is reviewed each month, and a list of items and quantities for purchase is prepared. One month, for example, the inventory of all raw materials used for production will be reviewed and the purchasing process initiated. Finished dose pharmaceuticals (injectables, tablets, capsules) are reviewed and ordered twice a year. The average lead time for orders is about 12 months. For items with an estimated value of about U.S.$12,000, purchasing can be done through restricted tender, whereby a minimum of 5 bids must be solicited from known suppliers. Above that amount an open tender is required. Tenders are publicized through the local paper and through Malaysian embassies overseas. Detailed specifications and bidding forms are provided for potential suppliers. Once offers are received they are collated and presented to weekly meetings of the Tender Board for supplier selection.

Costa Rica -- The purchasing process for the Social Security Fund is based on a continuous computer-based inventory and occurs throughout the year. There are approximately 50 purchases per year of about ten to twelve items each. The computerized inventory is updated daily with the records of all receipts to and issues from the Central Warehouse. The status of any product can be ascertained instantaneously on a screen or a printout.

Every three weeks, roughly, a computer listing is produced which gives the approximate expected duration of the current stock at the current consumption rate. This listing then determines when orders are initiated. Experience has shown that an 8 month lead time is about right for drug purchases, so orders are usually initiated when the current stock reaches an expected duration of 8 to 9 months.

Items with an estimated purchase price of less than U.S.$1,000 are bought directly, items costing between U.S.$1,000 and 5,000 are bought through private bids (restricted tenders) and items costing more than U.S.$5,000 are purchased through public bids (open tenders). Direct purchase of orders over U.S.$1,000 is used only in emergency situations. The public bids are truly public in that calls for bids are widely published: bids are opened publicly and results are published publicly. Once a bid is awarded, other suppliers have 45 days to appeal the decision. To facilitate bid processing, a maximum of 12 items is allowed on any one public bid.

Figure III.B.5.

Sample Drug Supply Contract

MINISTRY OF HEALTH
DEPARTMENT OF MEDICAL SUPPLY
GENERAL CONDITIONS OF CONTRACT

Terms 1. Quotations are C.I.F. Port Seatown unless otherwise stated.

Price 2. The contract price is firm and payable in national currency at the parity rate prevailing on the date of this contract award. If the contract price is subject to variation, the formula for such variation must be stated in the offer. Any subsequent price variation must be requested in writing and approved prior to delivery.

Payment 3. Payment will be made in National Currency on arrival of goods at Port Seatown. This Office shall have the right to inspect all goods prior to authorization of payment and to reject goods which do not conform to all clauses of this Contract. Rejected supplies will be returned to the Supplier at his expense.

Quality 4. The supplies shall conform to acceptable pharmacopoeial standards as specified in the Supplier's original offer. The Supplier shall furnish with each consignment a Certificate of Quality issued by the Supplier's national drug regulatory agency or by an independent quality control center previously approved by this Office.

Labeling 5. All external and internal containers should be labeled with the name, dosage form, strength, and quantity of the item enclosed. All labels should bear the International Non-Proprietary Name specified in the Call for Offers. Any expense involved in relabeling external or internal containers will be charged to the Supplier. Supplies not properly labeled may be returned to the Supplier at his expense.

Specifications 6. Supplies should conform to the specifications listed in the Call for Offers. Alterations or deviations specified in the Supplier's original Offer are acceptable unless otherwise stated.

Cold Storage 7. Items, such as vaccines and insulin, which require cold storage should be shipped COLD CHAMBER CARGO and labeled.

Performance Bond 8. The successful tenderer may be called upon, within one week after acceptance of the tender, to deposit an amount equal to 2-1/2% of the total value of the offer. This amount will be forfeited if the contract is not completed within the time limit and to the satisfaction of this Office.

Default 9. Should the Supplier fail to:
(a) deliver the supplies by the specified date or to the specified port; or
(b) replace, within time limited by this Office, any rejected supplies; or
(c) comply with each and every other condition of this Contract;
the Government may do either or both of the following:
(a) after notice to the supplier, nullify this Contract and obtain needed supplies from other suitable sources;
(b) recover from the Supplier any losses sustained by this Office resulting from the Supplier's failures.

Delivery 10. Delivery of supplies shall be made when specified in the Call for Offers, unless an alternative delivery date has been agreed upon in writing.

Indemnity 11. The Supplier shall indemnify this Government against all claims and the cost of defending or settling such claims which are related to patent rights, trademarks, designs, and royalties.

Packaging 12. Supplies must be packed in immediate and external export containers, suitable to withstand rough handling in transit and storage under tropical conditions. The humidity will be between 75% and 100% and high temperatures will be 80° to 90°F. On arrival at their ultimate destination within the country supplies should be free from damage. Containers should be sealed in a manner which makes tampering with the pack during transit easily detectable. The Supplier shall be liable for all loss, damage, or expense due to insufficient or unsuitable packing.

Expiry Date 13. Unless otherwise specified in the Call for Offers, all items which have a shelf-life must show dates at least 2 (two) years from the date that supplies are received and accepted by this Office.

Unique Identifiers 14. All immediate and external containers should bear the words, "Ministry of Health" and all tablets and capsules ordered in quantities in excess of 500,000 must be embossed with the letters "MH" on each tablet or capsule. Applications for exemption from this requirement must be made at the time Offers are submitted.

Import Documents 15. The Supplier is responsible for providing this Office with all documents necessary for taking possession of supplies and clearing them from the port of delivery. The Supplier shall be held accountable for any expenses or losses incurred by incorrect, incomplete, or late provision of documents by the Supplier.

2. CONTRACT TERMS

The purchasing of drugs is a specialized function requiring a great deal of care on the part of the buyer. Details such as the specification of the drug, quality standards required, type of packing, last date of shipment, etc. are all very important. In some cases, even a slight deviation from the specifications for a drug or a delay in shipment by the supplier will cause substantial losses or added expense. On the other hand, if the procurement office places a special order and then tries to revoke or deny the order, the supplier may have trouble selling this consignment of drugs to another user.

Therefore, in international trade, both the buyer and the seller are protected by a written contract. Those involved in purchasing drugs on behalf of public supply programs should become familiar with such contracts. Important contract terms are discussed below and an illustrative contract is shown in Figure III.B.5.

In many cases a supply contract serves as a statement of terms and is distributed with the call for offers. It is a condition under which a supplier may submit a bid, then, that he is willing to accept all of the publicized contract terms.

a. Trade Terms

Between the supplier's factory and the government's warehouse are a large number of activities and expenses involved in the transport of drugs and in safeguarding them from various risks. The division between buyer and seller of the costs and responsibility for making delivery arrangements is determined by the trade terms. Trade terms, which have evolved over many years, were standardized by the International Chamber of Commerce in 1953, when it published a set of interpretations which have become known as "Incoterms 1953" (see chapter references). Figure III.B.6. summarizes the four trade terms most commonly used for government supply programs and Appendix III.B.1. summarizes buyer and seller responsibilities under all trade terms.

The specification of trade terms -- usually done by the buyer -- is important since it determines the cost and, to a lesser extent, the speed with which drugs are delivered. Of the four terms listed in Figure III.B.6., C.I.F. terms require the least amount of expertise and knowledge of international trade on the part of the procurement office. For this reason, C.I.F. terms are generally preferable for new programs.

Large governments sometimes provide their own insurance, making C. & F. terms more attractive. For many developing countries, transportation routes are limited and economical delivery of goods from overseas requires a detailed knowledge of these routes. If a supplier is chosen who is unfamiliar with local trade routes and the procurement office is experienced in this, then F.O.B. terms may be preferable.

In general, the freight cost is about 10% and insurance about 1% of the F.O.B. cost. Even if C.I.F. prices are used, buyers often insist that freight, insurance, and F.O.B. rates be indicated separately. The contract may require

that the F.O.B. portion remain unchanged, but that the C.I.F. price may be adjusted for actual freight and insurance costs.

Figure III.B.6.

Comparison of Common Trade Terms

TERM	SUMMARY OF RESPONSIBILITIES	ADVANTAGES	DISADVANTAGES	CONDITIONS FAVORING USE
C.I.F. (cost, insurance, freight)	The seller covers all charges up to the arrival of the vessel at the buyer's port. This would include the F.O.B. price, freight, and insurance. Most buyers insist on obtaining a breakup of the total C.I.F. price into F.O.B., freight, and insurance components.	On the basis of such a quotation it would be possible to establish a letter of credit.	Sometimes it is less expensive for the buyer to acquire the insurance directly or to insure through a government agency.	These are the usual terms quoted and accepted for international trade.
C.&.F. (cost and freight)	This price covers the cost of the goods up to the point of shipment, i.e., the F.O.B. price, and the cost of freight.		Does not reflect the cost of insurance. If prices obtained from different manufacturers are to be compared, it may be necessary to make a suitable adjustment to the C.&.F. price to reflect the C.I.F. price.	Useful if the buyer wishes to insure the goods himself.
F.O.B. (free on board)	This is the price of a product when it has reached the point of shipment. This would consist of the exworks price together with any inland transportation costs involved in bringing the goods from the factory up to the port.		These terms are rarely quoted in practice for imports. Difficult for buyer to arrange transportation for foreign shipments.	Useful only if the buyer can arrange insurance and transportation, and can do so less expensively himself.
Exworks (at the factory)	This is the price of a product when bought from the factory itself and does not include transportation costs or insurance charges.	Usually useful for local sales.	These terms are rarely quoted in practice where goods have to be imported.	Useful when the buyer himself would make arrangements to collect the goods from the manufacturers or entrust this task to a third party.

b. Price and Currency

A difficult problem in international competitive bidding and supply contracting is that of currency conversion for bid comparison and, ultimately, for payment. The policy of the procurement unit with regard to this issue may have an important influence on the willingness of suppliers to participate and on the prices quoted.

Bid Comparisons

Various methods exist to allow price comparisons among many tenders. The International Bank for Reconstruction and Development (IBRD) Guidelines suggest that comparisons should be based on the official rates of exchange prevailing on the days bids are opened, with the stipulation that the rates applying at the time of award should be used, if these rates have changed from the time the bids were opened. The following table illustrates how this rule would be applied to compare bids from the Suppliers A, B, C, and D:*

	Value of Bid in Local Currency on:			
Bid:	Date of Bid Submission	Date of Bid Opening	Date of Award	Date of Payment
A (in DM)	9.00	$ 9.90	$ 9.90	$ 9.90
B (in Yen)	9.60	9.60	10.08	10.08
C (in U.S.$)	10.00	10.00	10.00	10.00
D (in It. Lira)	10.60	10.60	10.07	9.57

On the date of bid submission, Supplier A had the most favorable price (9.00), but this was irrelevant, since Supplier B had the most favorable price when the bids were opened (9.60). However, according to the IBRD Guidelines, Supplier A would ultimately be awarded the contract, since its bid was the lowest on the date of the award. Changes in parity subsequent to the bid award resulted in Supplier D having the lowest bid at the time of payment. However, it would be purely speculative to attempt to anticipate changes in parity, and such speculation should be avoided in public procurement.

Whether the IBRD rule is followed or an alternative rule is adopted, the policy for bid comparisons should be clearly stated and adhered to consistently.

Payment Currency

The contract must specify the currency of payment, which is generally the buyer's currency, the supplier's currency, or a third currency widely used in international trade (e.g., DM or U.S.$). Some authorities recommend payment in the supplier's currency because it does not place the speculative risks associated with changes in the parity rate on the supplier. If such risks are placed on the suppliers, by requiring payment in local currency, then the

---

* Comparison adapted from Westring, 1977, p. 19.

suppliers are forced to include a contingency factor in their prices, thus raising their prices. In other words, specifying that payment will be made in local currency makes the cost of a drug more predictable for the procurement office, but it is likely to raise the total cost of drug supplies.

Where procurement offices are required to purchase supplies with prices expressed in their own currencies, the added cost of this "contingency factor" can be avoided by guaranteeing to the supplier that he will be able to convert any payment into his own currency at the rate of exchange which prevailed at the time the bid was awarded. Such an arrangement would, of course, require the official approval of the buyer's central bank, and it would be worthwhile only if the savings obtained by eliminating the supplier's need for a contingency factor were greater than the cost of paying for revaluations occurring between the time of awarding a bid and the time of payment.

Fixed Prices

Most pharmaceutical contracts are for products which are delivered within one year, and the supplier should be able to calculate his costs in advance and offer a fixed price (subject, of course, to the currency considerations just mentioned). Occassionally there is uncertainty about future trends in material costs, processing methods, supply quantities, or delivery period which might justify a fluctuating price.

Negotiation of a favorable fluctuating price contract can be complex* and the Guidelines for Procurement Under World Bank Loans specify that, "No price adjustments should normally be provided for goods to be delivered within one year."**

c. Payment Terms

The contract must also specify payment terms. These may vary from supplier to supplier, depending on the supplier's experience with the government program and the supplier's own financial need.

Letter of Credit

The most common payment is by an irrevocable Letter of Credit, an interbank document stating that a certain sum of money is available for the seller to claim from his bank as soon as he ships a consignment and presents the required documents. Other trade documents are described in Chapter IV.C.

Letters of credit can be costly for the procuring agency in terms of

---

* See Reisman, 1981, Chapter 2; Westring, 1977, Section A.3.4.

** Paragraph 3.10, subparagraph 5, as reprinted in Westring, 1977, Document CE.

interest and banker's charges. However, this form of payment substantially reduces the supplier's credit risk and may enable him to obtain short-term loans through his own bank. Therefore, the supplier should be able to make a much better offer than if he were given less security for payment.

Agreements which allow for some variability in price due to such things as changes in freight and insurance costs can be handled with a supplementary payment or refund at the time of delivery.

Deferred Payment (Commercial Terms)

The buyer and the seller may agree, with the approval of their respective banks, to payment either at the time of delivery of goods, or deferred for a period of 30, 60, 90, 120, or 180 days. This is a form of credit buying and the procurement agency must be careful not to over-extend itself by contracting for more supplies than it can ultimately afford. Several programs have begun purchasing through favorable deferred payment terms and later, after defaulting on payments to their suppliers, are forced to use only letters of credit.

Deferred payment has the advantage of providing the buyer with leverage against substandard or incomplete deliveries. The buyer simply withholds payment until the supplier replaces the shipment or adjusts the bill.

In comparing the total cost of using alternative suppliers, the "terms cost" should be carefully considered. The potential effect of the terms cost is demonstrated in this example: Supplier A requires a letter of credit and his agent is paid upon clearance of the goods from the wharf. Supplier B allows a period of 120 days (four months) from receipt of goods until payment. If the annual interest rate in the Purchaser's country is 12%, or roughly 4% for a four month period, then the ability to delay payment for four months is essentially a 4% savings. A method for calculating the terms cost is given in Kudrna, 1975 (see references).

d. Quality Standards

Most pharmaceutical products are manufactured in conformity with a pharmacological standard. It may be their own country's standard, or more universally known standards such as the British, United States, or International Pharmacopoeia.

National or international quality standards are organized by generic (medical or INN) name and not by the brand names of various companies. Where a product is not identifiable in any pharmacopoeia, the manufacturer's standard would have to be accepted by the buyer. It is useful for the supply contract to specify the range of acceptable standards.

Drug contracts should also specify what type of documentation of quality is required. Chapter III.D. considers quality control in greater detail and suggests that, for suppliers of uncertain reliability, a certificate of quality be requested from an independent laboratory or from a national drug control agency, as outlined in the WHO Certification Scheme (Appendix III.D.3.).

The supply contract is an essential link in any effective quality assurance program.

e. Nomenclature and Labeling

A great deal of confusion in drug supply systems is generated by the multiplicity of drug names (see Chapter II.A.). Most drug products and certainly all essential or basic drugs have an International Nonproprietary Name (INN), which can be written in several languages. This is in essence the internationally recognized medical or generic name for a drug. In addition, some countries have their own system of generic drug names which differs from the INN. Finally, for many drugs there is a host of commercial or brand names by which multinational pharmaceutical corporations and local enterprises market their drugs.

To minimize confusion in the selection, procurement, distribution, and use of drugs, one standard nomenclature should be specified in the supply contract -- preferably the INN in the most acceptable language (e.g., English, Spanish, French). Suppliers can readily identify their products by the INN, but it is often extremely difficult and time-consuming for a procurement unit or central medical stores to determine, after-the-fact, the medical name for a drug which has been labeled with only an obscure brand name or a nationally determined generic name in another language.

Specification of standard nomenclature is particularly important in supply agreements for donated drugs, since aid programs frequently receive drugs from a variety of commercial suppliers. Without standard labeling these donations may be more trouble than they are worth.

All internal and external packaging should be labeled with the drug name, dosage, and quantity enclosed.

f. Product Specifications

In addition to specifying that all drugs should be labeled according to a standard nomenclature, supply contracts should contain a section for detailed product specifications. These usually correspond to the details provided in the call for offers or other procurement documents. They need not be repeated in the supply agreement, provided it is clear to all parties which specifications apply.

Product specifications indicate the dosage form (e.g., tablet, liquid), the drug content (the exact number of milligrams or the acceptable range of milligrams), and any special characteristics such as "prolonged release", "in a preparation and container suitable for humid environments," or "in hermetically sealed polythene inners, large enough to be reclosed with a twist seal, containing 5,000 tablets, in tins with reclosable air-tight lids."

g. Financial Guarantees

In international trade it is sometimes difficult to be certain of the

reliability of suppliers. To encourage suppliers to live up to their obligations, financial guarantees are required by some governments.

Earnest money, bid bonds, or security deposits in the form of cash, certified check, bank draft, state bond, or other negotiable bank document may be required at the time a bid is submitted. This security, which may be 1% of the value of the offer, is forfeited if the successful bidder withdraws his offer or refuses to agree to the announced contract requirements. Bid bonds are refunded when the award is announced and all suppliers have accepted the contract terms.

Performance bonds, retention money, or other forms of security deposit in a negotiable fiscal document may also be required at the time a contract is awarded. This is to guarantee that the supplier who is awarded the bid fulfills all contract obligations. An amount of 2-1/2 percent is often used for this purpose, and rarely are deposits of over 5 or 10 percent required. The deposit is separate from documentation involved in the letter of credit and is returned only after goods have been received in the country and found to meet all contract standards and to be of acceptable quality.

By requiring financial guarantees the government may reduce the number of bidders and indirectly cause the price of drug supplies to rise. To avoid the need for financial guarantees and the associated increase in prices, procurement officials may restrict their purchasing only to suppliers of known reliability. Reputable suppliers are not likely to renege on an offer or default on a delivery. Mechanisms for assessing supplier reliability are considered in the following chapter.

Several large drug procurement programs include provisions for financial guarantees in their supply contracts, but require such payments only for new or previously unreliable suppliers. This appears to be an attractive compromise

h. Delivery Date

The date by which the seller is expected to ship the consignment is specified in the procurement agreement and is incorporated in the Letter of Credit. The implication is that the Bill of Lading, issued by the shipping company and signed by the master of the carrying vessel, should be dated on or before the last date of shipment specified on the Letter of Credit.

The bank is prevented from accepting a Bill of Lading dated after the last date for shipment, unless the buyer has agreed to the delay and the Letter of Credit is suitably extended. If orders are covered by import licenses issued by a Controller of Imports, an extension may also be needed from the Controller.

The term "delivery date" is usually used, but it really should be shipment date.

i. Patent Provisions

Most new drugs enjoy patent rights for periods ranging from 2 to 17

years. During these periods, other sellers are prevented from manufacturing and marketing these particular products without the consent of the patent holder.

Patent rights help the research-based multinational drug companies to recover the costs of drug development, but they are also one way in which these companies are able to maintain high profit levels on their products. The length of patents for pharmaceutical products varies from country to country. In some countries certain forms of patent exemptions have been given for pharmaceuticals.

Local patent laws are generally outside the realm of the minstry of health, but contract provisions regarding drug imports are not. Patent rights for such products may be handled in one of several ways, depending in part on local law and court rulings. The simplest practice is to place the responsibility for observance of patent rights on the supplier. One typical government drug supply contract specifies, "The contractor shall indemnify this government against all claims that may arise at any time on account of Patent Rights." With such contract provisions some programs have knowingly bought "pirated" products at lower prices and referred claims by the patent holders to the suppliers. Multinational pharmaceutical corporations have also been known to discourage the use of such products by underbidding the "pirate source" in future tenders.

Contract provisions regarding patent rights are an individual program decision based on international and local legal and economic considerations.

j. Packaging

Certain manufacturers, especially large scale producers, have standard packs. There are definite advantages in ordering standard packs and it is left to the buyer to adjust his pack sizes, wherever possible, to fall in line with the seller's standard packs.

Packaging should be sufficient to withstand the climatic and transport conditions prevalent in the importing country. The supply contract can make this supplier responsibility explicit.

k. Expiry Date

Pharmaceutical products have varying "Shelf-Lives". The expiry date is specified by the manufacturer and may range from 6 months to over 5 years. The process of deterioration or diminishing efficacy of drugs is usually hastened under poor storage conditions. More details regarding this problem are included in Chapter III.D.

Because of the length of time required for local distribution, supply programs often require that pharmaceutical products have a shelf life of at least two years from the time the product is received by the central medical store. It is sometimes difficult to obtain adherence to this provision, particularly with donated supplies. Limiting purchases to reliable suppliers and requiring financial guarantees can reduce the incidence of short-dated drugs.

Country Study III.B.2.

Monitoring Order Status in Sri Lanka

During its first few years of operation, the State Pharmaceuticals Corporation of Sri Lanka experienced many problems in procuring drugs. A large proportion of time in the supply department was utilized to attend to urgent requests made by the distribution department to expedite work in connection with the procurement of a large number of drugs which were constantly in short supply. This style of crisis management became increasingly worse with time, and therefore the management took immediate steps to conduct a survey of all procedures used by the supply department. With a view toward improving performance, this revealed that most problems resulted from the fact that the supply department lacked an effective system for monitoring and controlling outstanding orders and also was not in a position to expedite work on urgent orders.

The management realized the importance of reorganizing this department and introduced new systems and procedures to improve performance. One of the important features of the new system was to provide each subject clerk in charge of drug procurement with a manually operated control box for planning and controlling procurement activities. The box contained cards arranged in three colors to represent the three classes of drugs according to the VEN system of classification. Such a procedure would help to assign high priority to Class V life-saving drugs in monitoring performance. Each box was divided into several compartments by the use of wooden separators to signify important stages in the lead time period. A card located in any particular compartment signified the presence of one or more incomplete functions assigned to that compartment.

Work packages were assigned to each compartment, and consisted of an important function in the supply department itself, or a transaction required for related operations to continue in other departments such as wharf and inventory control. An entire work package had to be completed before a card could be moved from one compartment to a subsequent one.

All cards initially had to start from the first compartment (with the necessary information entered in pencil so that it could be reused) and remained there until an indent had been posted to the supplier. It passed through all other departments until it reached the last compartment when it was removed from the box completely.

In the case of partial shipments, a new card was introduced to represent the second installment and both cards were located in appropriate positions according to their order status.

Cards used in control boxes had a number of small spaces equal to the number of compartments. These spaces were for the purpose of entering the due dates or the length of time for a card to remain in any given compartment. The subject clerks would enter the due dates in appropriate spaces in reference to the standard time allowed to a particular compartment whenever a card was transferred to a subsequent compartment. In case certain cards remained in a particular compartment for more days than specified by the due date, they would be transferred to the front of the same compartment and secured with a red rubber band indicating that the progress with respect to these drugs was far behind schedule. Subject clerks and supervisors were to review all such overdue orders with the manager in charge of the department so that some corrective action could be taken as early as possible.

The subject clerk also entered any special observations under the space allocated for remarks on the control cards, such as poor correspondence, significant deviations from particulars stated in the original indent, e.g., pack size, strength, certificates, etc. This type of information would be useful in rating suppliers.

FUNCTIONS/TRANSACTIONS TO BE CARRIED OUT BY SUBJECT CLERKS
*(denotes a related function but not performed by a subject clerk)

1. *Tender offers received.
2. Extract names of tenders meeting basic requirements and prepare a summary sheet.
3. Forward summarized tender schedules to the technical manager for his comments regarding quality certificates, etc.
4. *Tender board decision.
5. Cable notification of award.
6. Prepare letter of credit, indent, and, if necessary, insurance documents.
7. On receiving a reply to the cable award, post the indent to supplier.
8. Post Standard Letter No. 1 to supplier approximately 3 days after completing (7) above.
9. Send copy of indent to the inventory control unit, which enters quantity on order into Kardex.
10. *Letter of credit dispatched to bank.
11. Post Standard Letter No. 2 if applicable.

12. Post Standard Letter No. 3 1-2 months after No. 2.
13. Provide information received from Letter No. 3 regarding status of order to inventory control unit.
14. Post Standard Letter No. 4 to supplier; send close to time when goods expected to be shipped.
15. Provide information received from Standard Letter No. 4 regarding status of order to inventory control unit and wharf department.
16. Check correctness of advanced documents with indents and forward them to the wharf department.
17. Follow up clearance of imports.
18. Record the issue of goods recieved note (GRN) and its reference number.
19. Correspond with supplier regarding damages, short shipments, etc.
20. Supply necessary data required by the merit rating system for supplier.

USE OF THE CONTROL BOX

Functions or tasks that have to be completed before a card can be transferred to the subsequent compartment	Compartment Number	Standard time allowed for the card to remain in the compartment.	Significance
1-9	1	2-1/2 months	Posting of the indent
10-12	2	1/2 month	Posting of the Letter of Credit
13-14	3	2 months	First notification of order status sent to Inventory Control Unit
15-16	4	3 weeks	2nd notification of order status sent to Inventory Control Unit
17-20	5	2 weeks	File is closed

CONCLUSION

When the control boxes were initially introduced there was a tendency on the part of subject clerks to revert back to their own methods of monitoring the status of outstanding orders, rather than use control boxes. This problem was soon rectified by providing training on procurement, inventory control, and on the use of control boxes. In addition to improving the overall planning and control of outstanding orders, the use of control boxes and standard forms was able to bring about the following benefits:

1. The concept of allocating work packages to each of the compartments of a control box helped those involved in procurement to understand better all steps involved in processing an order.

2. It was also possible to formalize the process of providing and receiving information from suppliers and other units of the organization such as inventory control. Allocating dates for completing work assigned to different compartments provided an easy method of identifying orders which were progressing behind schedule. As a result it was possible for subject clerks to take necessary action on these orders after consulting their superiors.

3. Since all subject clerks were expected to follow a similar system for processing orders, the task of supervision became much easier. Further, in case a subject clerk was absent it was quite easy for another to act on his behalf, as everybody was expected to follow a similar procedure in maintaining the control boxes.

The use of control boxes was an inexpensive, but yet very effective, method of exercising proper control on all outstanding orders.

1. Unique Identifiers

For purposes of security and easy identificaiton, some programs require that government supplies contain a government stamp, logo, or other unique identification. The nature and purposes of these identifiers are described in Chapter VI.C. Additional markings may be useful for special products such as vaccines, which require cold storage.

* * *

The preceding discussion of contract terms was intended to help procurement programs establish supply agreements which will assure reliable delivery of high-quality drug products. Specific provisions can be developed based on individual program experiences and needs. Supply agreements in themselves are not effective without conscientious supervision of the supply process by procurement and distribution officials. In particular, careful checking of drugs at the time they are received is essential to confirm supplier adherence to contract terms (see Chapters VI.C. and IV.D.).

3. MONITORING ORDER STATUS

Once a supply agreement has been reached, the buyer expects the goods to be shipped at the agreed-upon time. In practice, shipments are often delayed, and sometimes these delays are as long as several months. Furthermore, the buyer sometimes has responsibilities which, if not met in a timely fashion, can lead to further delays. Therefore, the procurement units have found it quite beneficial to monitor the status of all outstanding orders by maintaining a monitoring system and constant communication with suppliers.

Correspondence with Suppliers

At certain points during the lead time period, it is useful to have certain information from the supplier about each order. This can be obtained by writing individual letters to suppliers, but in practice the type of information to be provided to and obtained from suppliers is standard. Therefore, such routine correspondence with suppliers can be carried out using a set of standard forms which greatly reduce the time taken to prepare and type individual letters. Examples of standard letters employed for this purpose appear in Appendix III.B.2. These should be posted to suppliers at specific intervals during the lead time period, so as to obtain information regarding the status of orders.

Country Study III.B.2. illustrates the use of these letters in Sri Lanka. The experience of the State Pharmaceuticals Corporation of Sri Lanka indicates that there has been a very good response from suppliers to these standard forms. It has been possible to reduce a substantial amount of routine work, not only for the purchasing staff of the SPC, but for the supplier as well.

Figure III.B.7.

Wall Charts for Monitoring Order Status: Domestic Purchases, Foreign Purchases, and Donations

MINISTRY OF PUBLIC HEALTH
Department of Medical Supply

ORDER STATUS: DOMESTIC PURCHASES

Order Number	Originator	Description	1 Request received from Director of Procurement	2 Funds verified	3 Selection Committee or person appointed	4 Price Comparison for Minor Purchases form completed	5 Purchase Order forwarded for signature	6 Signed Purchase Order forwarded to Accounting	7 Transfer of Advance and Cash Order Receipt forms forwarded from Accounting to Finance	8 Trustee appointed	9 Check issued	10 Supplies picked up
D1												
D2												

MINISTRY OF PUBLIC HEALTH
Department of Medical Supply

ORDER STATUS: FOREIGN PURCHASES

Order Number	Originator	Description	1 Request received from Director of Procurement	2 Funds verified	3 Authorization from Minister's office to initiate foreign purchase process	4 Advertising begun (when called for)	5 *Pro Forma* invoices solicited	6 Comparison Work Sheet completed	7 Selection Made	8 Purchase order authorized by Minister's Office	9 Request from General Directorate of Medical Logistics to Directorate of Accounting for payment	10 Letter of Credit sent from Accounting to Bank	11 Letter of Credit executed	12 Supplies in transit/Estimated date of arrival	13 Supplies in Customs	14 Supplies transferred to point of storage
F1																
F2																
F3																

MINISTRY OF PUBLIC HEALTH
Department of Medical Supply

ORDER STATUS: DONATIONS

Order Number	Originator	Description	1 Formal request by Ministry/ Director of Medical Supply	2 Negotiations begin	3 Agreement reached/ Protocol signed	4 Supplies ordered	5 Supplies in transit/ Estimated arrival date	6 Supplies at customs	7 Supplies transferred to point of storage
N1									
N2									

A Card File for Monitoring Outstanding Orders

A government procurement unit may be involved in ordering hundreds of different drugs within the course of a year. In such an instance, it is useful to employ a simple system to monitor the progress made with regard to individual drugs on order.

One possible method of monitoring orders is to use a manually operated control box such as that described in Country Study III.B.2. Such a box would be provided to each supply clerk, and would contain cards of three colors to represent the VEN (Vital, Essential, Non-essential) classifications for drugs (see Chapter VI.B.). In monitoring orders, clerks would assign higher priority to life-saving drugs. With this system, cards would be moved from the first compartment in the box to the last, as functions were completed, and then removed from the box completely.

The supply clerks would periodically review all overdue orders with the manager in charge of the department so that corrective action could be taken as early as possible. They would also enter any special observations under the space allocated for remarks on the control cards, such as poor correspondence, significant deviations from particulars stated in the original indent, e.g., pack sizes, strength, certificates, etc. This type of information would be important for merit rating of suppliers (see Chapter III.C.).

Wall Charts

Systems for monitoring order status may be used to follow the entire procurement cycle. Wall charts for such a purpose were designed for use in a large supply program in one central Asian country (Figure III.B.7.). Three charts were posted in the central procurement office, one chart for domestic purchases, one for foreign purchases, and one for donations. (Predictable and dependable delivery of donated items was just as important as the arrival of purchased items, thus a separate order status chart.)

The steps in the procurement cycle varied slightly according to the supply source and this is reflected in the differences between the three charts.

SUMMARY

The procurement method used and contract terms are critical determinants of purchase price, drug and package quality, and supplier performance. These factors deserve special attention in the establishment and management of a procurement system.

Hidden costs, unanticipated expenses resulting from poor quality in drugs or packaging and poor supplier performance, can increase true costs.

Four procurement methods are commonly used, each having specific advantages and disadvantages:

(1) Open Tender, a public or unrestricted bid, usually results in the lowest prices, but requires the most staff time and the closest monitoring of supplier performance.

(2) Restricted Tenders, in which suppliers must be registered and approved in advance, often obtain favorable prices, but with less burden on the supply staff.

(3) Negotiated Procurement, useful for selected items where likely suppliers are well known and can be approached directly.

(4) Direct Procurement, at posted wholesale or retail prices; usually the quickest, easiest, but most expensive method.

Contract terms should maximize the likelihood of satisfactory supplier performance, without leading suppliers to raise prices. Key points include:

- Trade Terms -- C.I.F. (cost, insurance, freight) most common.
- Price and Currency -- Currency conversions and currency of payment should be spelled out in advance, can affect costs significantly.
- Payment Terms -- Commercial (deferred) terms preferable, but letter of credit usually required.
- Quality Standards -- Specification of standard and acceptable proof of quality.
- Nomenclature and Labeling -- All products should be labeled with their medical (generic) name.
- Product Specifications -- Exact name, dosage form, and special requirements must be stated clearly.
- Financial Guarantees -- Sometimes required to assure that successful bidders fulfill their obligations.
- Delivery Date -- In accepting an order, supplier agrees to a specific delivery date, to which he should be held.
- Patent Provisions -- Many drug products are under patent. Liability for variations from patent restrictions should fall with supplier.
- Packaging -- Supplier should be expected to package drugs for the environment products will be used in.
- Expiry Date -- In general, most drugs should have a shelf-life of at least two years when they arrive in the country.
- Unique Identifiers -- To identify drugs as public supplies.

Monitoring Order Status to expedite delivery and port clearance can have large payoffs in terms of increased supply efficiency.

CHAPTER III.B. REFERENCES

Ammer, D.S.: Purchasing and Materials Management for Health Care Institutions. Lexington, MA: D.C. Heath and Co., 1975.

Bailey, P.J.H.: Purchasing and Supply Management, 2nd Edition. New York: Chapman and Hall, 1969.

Combs, P.H.: Handbook of International Purchasing, 2nd Edition. Boston: Cahners Publishing Co., Inc., 1976.

Gasdia, S.D. and Brennan, E.C.: Purchasing Pharmaceuticals on a Competitive Basis. Hospital Formulary Management, August-September, 1968.

International Chamber of Commerce: International Rules for the Interpretation of Trade Terms. Paris: International Chamber of Commerce, 1977. (English-French).

Kudrna, D.A.: Purchasing Manager's Decision Handbook. Boston: Cahners Publishing Co., Inc., 1975.

United Nations: Supply Management: Towards Better Use of Equipment and Material Resources in Developing Countries. New York: United Nations Department of Economic and Social Affairs, ST/ESA/SER.E/16, 1978.

Westring, G.: International Procurement: A Training Manual. New York: United Nations Institute for Training and Research, 1977.

Appendix III.B.1.

Summary of Internationally Recognized Trade Terms

S: Seller responsibility
B: Buyer responsibility
X: Point where buyer takes possession
O: Point where buyer takes ownership

STEPS IN TRADE	TRADE TERMS										
	"Ex Works"	FOB Seller's Plant	FOB Seller's Plant Freight Allowed	FOB Seller's Plant Freight Prepaid	FOB Vessel Port of Export	FOB Vessel Port of Import	FAS Port of Export	FAS Port of Import	CIF Port of Import	C&F Port of Import	FOB Buyer's Plant
Seller's plant	BXO	BXO	BO	BO	S	S	S	S	S	S	S
Pay local sales tax	S	S	S	S	S	S	S	S	S	S	S
Provide invoice and packing slip	S	S	S	S	S	S	S	S	S	S	S
Provide certificate of manufacture	S	S	S	S	S	S	S	S	S	S	S
Provide certificate of origin	S	S	S	S	S	S	S	S	S	S	S
Load onto carrier (rail or truck)	B	S	S	S	S	S	S	S	S	S	S
Provide and pay inland transportation insurance	B	B	B	S	S	S	S	S	S	S	S
Provide clean inland bill of lading	B	S	S	S	S	S	S	S	S	S	S
Pay for demurrage	B	S	S	S	S	S	S	S	S	S	S
Pay cost of inland transportation	B	B	B	S	S	S	S	S	S	S	S
Obtain export license	B	B	B	B	S	S	S	S	S	S	S
Pay fees for export license	B	B	B	B	S	S	S	S	S	S	S
Deliver to port	B	B	SX	SX	S	S	S	S	S	S	S
Unload at port	B	B	B	B	S	S	S	S	S	S	S
Pay storage charges	B	B	B	B	S	S	S	S	S	S	S
Pay port charges	B	B	B	B	S	S	S	S	S	S	S
Pay export taxes	B	B	B	B	S	S	SXO	S	S	S	S
Give notice of name of vessel	B	B	B	B	B	S	B	S	S	S	S
Give notice of sailing date	B	B	B	B	B	S	B	S	S	S	S
Give notice of loading berth	B	B	B	B	B	S	B	S	S	S	S
Give notice of required delivery time	B	B	B	B	B	S	B	S	S	S	S
Load on ship	B	B	B	B	S	S	B	S	S	S	S
Pay loading charges	B	B	B	B	S	S	B	S	S	S	S
Provide clean ocean or air bill of lading	B	B	B	B	SXO	S	B	S	S	S	S
Provide war risk insurance	B	B	B	B	B	S	B	S	S	B	S
Provide marine insurance	B	B	B	B	B	S	B	S	S	B	S
Pay cost of ocean or air shipment	B	B	B	B	B	S	B	S	S	S	S
Unload at port of importation	B	B	B	B	B	BXO	B	SXO	BXO	BXO	S
Pay unloading charges	B	B	B	B	B	B	B	S	B	B	S
Pay storage charges	B	B	B	B	B	B	B	B	B	B	S
Provide import license	B	B	B	B	B	B	B	B	B	B	S
Pay customs duties	B	B	B	B	B	B	B	B	B	B	S
Pay import taxes	B	B	B	B	B	B	B	B	B	B	S
Pay sales taxes	B	B	B	B	B	B	B	B	B	B	S
Provide clean inland bill of lading	B	B	B	B	B	B	B	B	B	B	S
Pay inland transportation costs	B	B	B	B	B	B	B	B	B	B	S
Pay demurrage costs (generated at port)	B	B	B	B	B	B	B	B	B	B	S
Provide inland insurance for transportation	B	B	B	B	B	B	B	B	B	B	S
Receive at inland point	B	B	B	B	B	B	B	B	B	B	BXO
Unload from carrier	B	B	B	B	B	B	B	B	B	B	B

This checklist should not be interpreted as meaning all these steps are necessary or required. Rather it is intended to reflect most of the steps generally required when shipments are made from one country to another.

Adapted with permission from Combs, C.B.I. Publishing Co., 1976.

Appendix III.B.2.

Standard Letters to Suppliers Regarding Order Status

Standard Form No. 1

Ministry of Health
Department of Medical Supply

Dear Sirs,

RE: Order Acknowledgement
Indent No. _____

We believe that our Indent No. _____ dated _____ has been received by you now.

Please confirm, by signing and returning the duplicate of this letter, that you will comply with:

(a) All Terms & Conditions;
(b) Delivery schedule indicated on the Indent;
(c) Quality standards and specifications referred to against every item ordered.

If by any chance you feel that you cannot comply with any of our requirements, you could take this opportunity to let us know the reasons why you cannot do so.

In the absence of such comments, we would assume that you are complying with all requirements and conditions and the delivery requirements stated in our indent. Any unexplained lapse on your part hereafter would be viewed very critically by us, and it will most certainly affect the good business relationship we have with you.

_____
Signature of Supplier

Date _____

_____
Director of Procurement

Date _____

Standard Form No. 2

Ministry of Health
Department of Medical Supply

Dear Sirs,

RE: Details of Letter of Credit
Indent No. _____

We confirm having established a Letter of Credit to cover the above indent.

Please confirm, by signing and returning the duplicate of this letter, that the entire order will be shipped as requested and as per the delivery schedule given in the Indent.

1. Letter of Credit No. _____
2. Date Established: _____ by cable/airmail.
3. Through _____
   (Please contact them for further details)
4. Last date for shipment: _____
5. Partial Shipments -- Allowed/Not Allowed.
6. Transshipment -- Allowed/Not Allowed.
7. Airfreight -- Allowed/Not Allowed.
8. A detailed Analytical Certificate is requested from __
   _____

We confirm that shipment will be effected as per Terms & Conditions of L/C No. _____

_____
Signature of Supplier

Date _____

_____
Director of Procurement

Date _____

Standard Letter No. 3

Ministry of Health
Department of Medical Supply

Dear Sirs,

RE: Order Status
Indent No. _____

Please complete the undernoted and return the duplicate to us by express airmail.

1. All items in Indent will be completed by the latest date for shipment -- i.e., _____ YES/NO.
2. We have booked freight. YES/NO
3. The name of vessel is _____
   E.T.D. (Port of Loading) _____
   E.T.A. _____
4. (If the answer to (1) is negative)
   (a) Only the undernoted items will be shipped. (Please indicate items and quantity)
   _____
   _____
   _____
   _____
   (b) The production of the balance will be completed by: _____
   (c) The reasons for delay are: (in detail against each item) _____
   _____
   _____

_____ Signature of Supplier

_____ Director of Procurement

Date _____

Date _____

Standard Letter No. 4

Ministry of Health
Department of Medical Supply

Dear Sirs,

RE: Shipment Information
Indent No.

Please complete the undernoted and return the duplicate by express airmail.

1. Entire order/Part order has been shipped. YES/NO
2. Name of vessel: _____
3. E.T.A. _____
4. (If only part shipment) Only the undernoted have been shipped.

   Item | Quantity

   _____
   _____
   _____
   _____
5. Advance shipping documents (as per documentation instructions given with the indent) posted YES/NO
6. Date Posted: _____
7. Original documents negotiated through Bankers. YES/NO
8. Date negotiated: _____
9. If goods have not been shipped, reasons for non-shipment (in detail with likely delivery date)
   _____
   _____
   _____
10. Quality Certificate posted. YES/NO

_____ Signature of Supplier

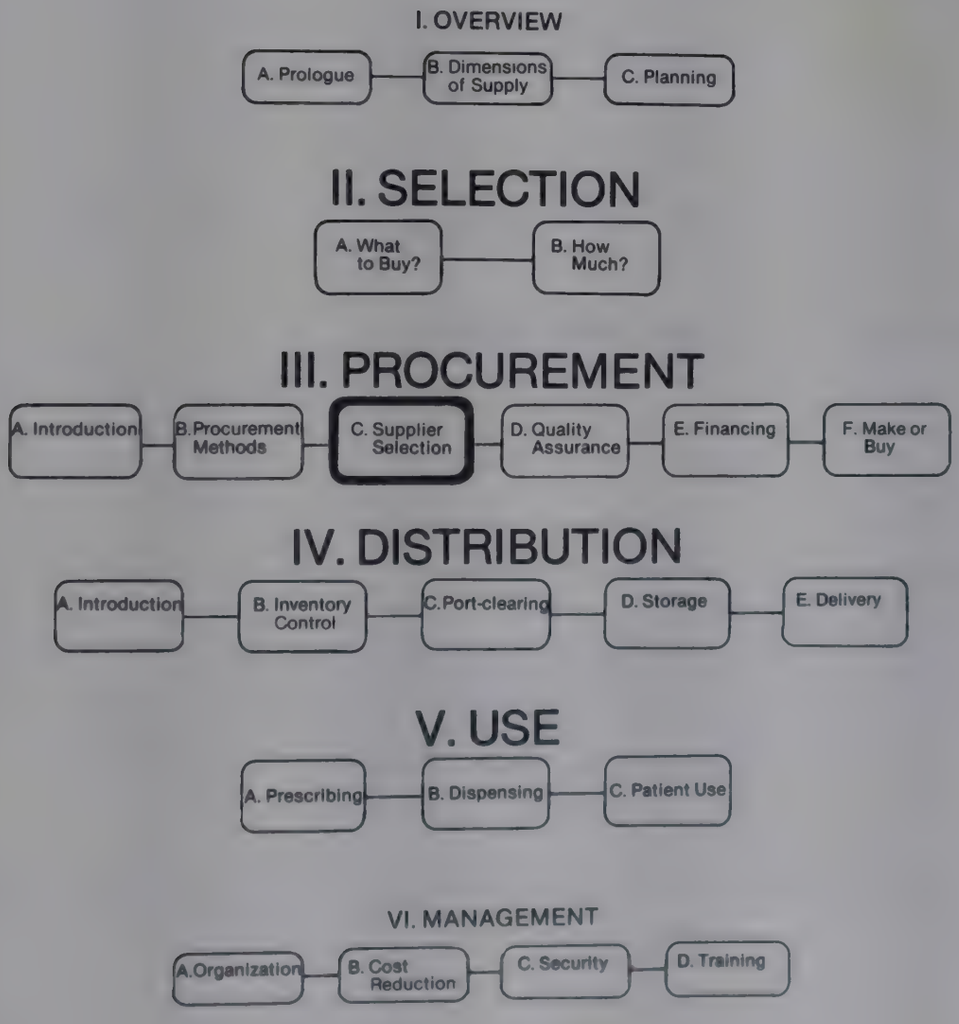
_____ Director of Procurement

Date _____

Date _____

Chapter III.C.

Whom to Buy From: Locating and Selecting Suppliers



	Page
1. SUPPLY SOURCES	150
2. LOCATING SUPPLIERS	152
3. SUPPLIER RELIABILITY	153
a. Evaluating New Suppliers	155
b. Monitoring Supplier Performance	156
4. SELECTING SUPPLIERS	159
a. Decision-Making Authority	159
b. Selection Criteria	162
5. PURCHASING THROUGH LOCAL AGENTS	165
SUMMARY	167
REFERENCES	168
APPENDICES	
III.C.1. Calculating Hidden Cost Ratios	169
III.C.2. Calculating Expected Delivery Dates	171
III.C.3. Organizations and Information Sources for Locating Pharmaceutical Suppliers	172
III.C.4. Sample Supplier Registration Forms	174

Whom to Buy From: Locating and Selecting Suppliers

The process of locating and selecting suppliers has a profound impact on both the quality and cost of the drugs acquired by public health programs. Inadequate quality assurance in the selection process may result in the purchase of drugs which are ineffective, unsafe, or even deadly. Hidden costs resulting from late deliveries, complete default on confirmed orders, losses due to poor packaging, short expiration dates, and other factors attributable to an unreliable supplier may raise the actual cost of purchasing a drug to several times the original contract cost.

It would greatly simplify the purchasing process if it were possible to prepare and circulate a list of reliable international suppliers and their prices for each pharmaceutical product. However, the pharmaceutical industry is too dynamic and international pharmaceutical distribution networks too diverse for such a list to be created. New suppliers are constantly coming into the market, while other suppliers are changing to new fields, merging, or going out of business altogether. New companies often have difficulties with quality control and packaging for export during their first few years of production, but after three to six years may become reliable low-cost producers. At the same time, a company long known for high quality products and prompt service may become seriously deficient as a result of changes in central management or regional distributors. A multinational company offering an attractive price may provide excellent service in one country and horrendous service in a nearby country solely because of its choice of in-country representatives.

For some quantities of drugs purchased, an international agency such as ECHO may be the least expensive source of drugs, while for other quantities, a multinational corporation may be least expensive. Even with products for which only one multinational company has the production know-how, intra-firm arrangements and licensing arrangements with other firms may result in what are effectively multiple sources and multiple prices. One West African country found that a single-source brand name product was obtainable at a lower price from an American subsidiary than from the Swiss parent company. A western Pacific country has found that some single source products are less expensive when bought directly from the British parent company than when they are bought from the Australian agent; and so on. (Appendix III.C.3. lists organizations and information sources which may be of value in locating suppliers.)

An efficient purchasing office, therefore, must know how to select low-cost suppliers and how to assure their reliability with respect to quality and service. The first step is to locate the broadest range of suppliers willing and able to serve the country's public health programs. The six principal sources of pharmaceuticals for public programs with the most common means of locating specific suppliers are listed in Figure III.C.1. Once a broad range of suppliers has been located, the procurement staff must concentrate on developing a good knowledge of the suppliers. Knowing each supplier's reliability, versatility, and business practices is invaluable in assuring a steady supply of economically-priced, high quality drugs.

ASSESSMENT GUIDE III.C.
Locating and Selecting Suppliers

- Who currently supplies pharmaceuticals for public health programs? How many different suppliers are there? What kind of suppliers are they? Bilateral aid programs? International procurement services (e.g., Crown Agents)? Multinational drug companies? Local import agents?

- How are previous suppliers informed about tenders? How are new suppliers located? Are there a sufficient number of potential suppliers for each product? Are there too many offers when tenders are announced?

- Is the quality and service reliability of new suppliers evaluated? If so, how? What information is used to determine the acceptability of new suppliers?

- How often is the drug supply program troubled by a supplier who fails to fulfill his obligation? Who sends improperly packaged or faulty drugs? Who fails to provide needed importation documents? Whose drugs are found to lack potency when administered to patients? How are a supplier's bad performances reflected in future supplier selections?

- Who chooses specific suppliers from among the potential candidates? Is it a single individual or a committee? What are the qualifications of the individual or committee members? What kinds of influence are brought to bear on the individual(s) who select the suppliers?

- What criteria are used to select suppliers? Price alone? Quality? Past performance? Delivery date? Donor agency restrictions? Are these criteria written down and closely adhered to, or are they used rather informally?

- What role do local agents play in locating, selecting, and conducting business with pharmaceutical suppliers? Do they seem to facilitate the procurement process or hinder it?

1. SUPPLY SOURCES

Government production, local private manufacturers, and foreign manufacturers are primary sources of pharmaceuticals, since these groups do the manufacturing themselves. Donors, international procurement services, and independent foreign exporters are secondary sources, since they generally do not manufacture pharmaceuticals, but obtain them from an independent producer.

When obtaining drugs from secondary suppliers, it is important to determine who their primary supplier is, since the quality of pharmaceuticals and their containers is determined by the manufacturer. Donors and international

Figure III.C.1.

Locating Supply Sources

Sources of Pharmaceuticals	Means of Locating Specific Suppliers
Primary sources	
1. Government Production	• Intra-Government negotiations
2. Local Manufacturers	• Locally Publicized Notice • Direct Inquiry to Individual Suppliers
3. Foreign Manufacturers	• Locally Publicized Notice (Contact through local agent)
a. Multinational Firms Based in Developed Countries	• Internationally Publicized Notice • Direct Inquiry Through Local Agents • Direct Inquiry to Home Office
b. Firms in Developing Countries	• Inquiry through national trade associations (See Appendix III.C.3.)
Secondary Sources	
4. Donations from Bilateral Aid Programs, International Agencies, and Charitable Organizations	• Survey Government Agencies to determine Current Sources • Direct Inquiry to Local Offices of UNICEF, foreign aid programs, religious and charitable groups, etc. • Direct Inquiry to Home Offices of Potential Donors
5. International Procurement Services	• Direct Inquiry (See Appendix III.C.3.)
6. Independent Foreign Exporter	• As for Foreign Manufacturers

procurement services generally have reliable means of assuring quality, but the buyer should inquire as to what these means are. Independent foreign exporters vary widely in their quality assurance practices and should generally be required to state the primary manufacturer at the time offers are considered.

Drug manufacturers can be classified in several different ways. One important distinction is between research-based producers and non-research-based producers. The well-known multinational drug companies are research-based in that their reputation and, to a large extent, their profitability depends upon new drugs developed through research and vigorously promoted by brand name. Nevertheless, many such firms do produce a line of drugs which they sell by the medical (generic) drug name at a lower price than their brand name

DR-400
04700
COMMUNITY HEALTH CELL
LIBRARY
AND
DOCUMENTATION

products. These drugs are often made on the same production line and sometimes in the same batch as the brand name product. The quality standards are identical; only the packaging and appearance of the drug is different.

Non-research-based firms include a wide variety of producers ranging from small, new, one-factory local companies to large national producers such as the state pharmceutical corporations in some socialist economies. These manufacturers are often referred to as "generic drug houses," since they frequently market their drugs only by the medical drug names.

Research-based transnationals and non-research-based firms should be considered equally and evaluated by the same criteria. The internationally known research-based companies are frequently, but not always, more expensive. At the same time they are not always the reliable suppliers that they are expected to be. On the other hand, many local non-research-based companies produce drugs of high quality.

International procurement services such as UNICEF and ECHO (Appendix III.C.3.) are generally non-profit public service groups. Some, such as Crown Agents, charge a commission. These organizations vary with regard to their selection of drugs, prices, means of quality assurance, payment terms, and restrictions placed on the buyer. Equally important is the fact that they vary in the kind of service which they provide. Some will provide selected drugs specified by the purchasing office and ship them quickly from their own warehouse (e.g., ECHO). Others are only purchasing agents; they must go through the sometimes lengthy process of negotiating prices for each order. They then arrange shipment from the primary supplier to the buyer (e.g., Crown Agents).

Because of the variation in the international procurement services and because of the limitations which some have, they should be evaluated by the same criteria used for other sources of supply.

Independent foreign exporters -- also known as "jobbers" -- are in some countries under less strict control than are the manufacturers. In the United States, for example, the government has little control over exporters who do not undertake manufacturing themselves. Also, good manufacturing practices are enforced less rigorously for export products in some countries.

2. LOCATING SUPPLIERS

An established public procurement program may do business with as many as 100 to 150 suppliers over a period of several years, but experienced purchasers find that about 10 percent of their suppliers receive about 80 percent of the orders. Thus, most drugs will come from one of ten to twenty suppliers. It is nevertheless important -- especially during the early years of a program -- to locate and attract bids from a wide range of potential suppliers. The advantages of this are that (1) lower prices are likely to be found, (2) more reliable suppliers are likely to be found and the less reliable ones can be more quickly dropped, (3) necessary, but unusual, drugs or dosage forms can be more readily obtained, and (4) more options are then available in case emergenc supplies are needed.

There are certain occasions when direct inquiries to local and foreign suppliers are the most useful means of attracting a bid. This is often true during the initial stages of establishing a purchasing system, and at later stages when none of the purchaser's current suppliers are able to provide a specific drug or drug formulation at a reasonable price.

When making direct inquiries to foreign offices it is advisable to limit inquiries to suppliers in countries which have established trade routes with the purchasing country and which are known from previous experience to enforce good manufacturing practices.

Advertisement of public tenders aims at attracting a large number of local or international bidders. Countries which publicize widely their intent to purchase and which allow sufficient time (6-8 weeks) for suppliers to submit their offers appear to obtain the best prices for drugs. Tenders can be publicized through local newspaper notices, international notices, and direct mailings to known suppliers.

International notices can be distributed through: newspapers and trade journals with wide international circulation, trade representatives in the local diplomatic missions from supplying countries, the purchasing country's diplomatic missions in supplying countries, and government agencies responsible for foreign trade in the supplying countries. Widespread international publicity for drug purchases should be approached with some caution, however, since the purchaser can easily be deluged with an unmanageable volume of supply offers.

Some countries which generally purchase only from registered suppliers publicize their intent to purchase through an international notice in addition to contacting their registered suppliers directly. This practice provides a second avenue for informing registered suppliers in case the mail fails to reach them, and also may interest new suppliers in registering with the purchaser.

Even when all foreign suppliers are represented by local agents who can communicate tender notices to the home office, it is sometimes advisable to publicize the notice through international channels. These channels are often faster and sometimes more reliable than the local agent in bringing news of a tender to the foreign supplier. Earlier notification allows the supplier more time to prepare an offer and makes it likely that he will submit an offer.

3. SUPPLIER RELIABILITY

Determining supplier reliability is one of the essential tasks of an effective procurement staff. Each year public drug programs lose substantial amounts of money and the public health is endangered because of poor supplier performance. In 1976, the social security program of one Central American country rejected 17% of the deliveries made to its warehouse because the products failed to pass quality control tests. In Asia, one state pharmaceutical corporation annually spends thousands of dollars for air-freighting large quantities of essential drugs to compensate for late deliveries. Inadequate packaging by low-bidding suppliers attempting to minimize their costs results

in losses of 5 to 10 percent of the drugs purchased by some public supply programs.

An effective procurement staff must develop a system of determining supplier reliability and eliminating those suppliers whose performance is clearly substandard.

Figure III.C.2.

Evaluating New Suppliers

1. Quality Control
   - Does the supplier conform to standards of good manufacturing practices? (See Chapter III.D.)
   - Does supplier have on-site quality control laboratory or arrangements with an immediately accessible laboratory?
   - What tests -- chemical, biological, stability, accelerated stability, etc. -- are routinely performed during and after the manufacturing process?
   - Are special tests performed for stability in tropical environments?
2. Inspection
   - What official government agencies or other reputable international organizations have inspected the manufacturing facilities?
   - What are the results of the most recent inspections?
3. Personnel and Facilities
   - What are the qualifications of top production and quality control personnel?
   - What is the capacity of the supplier's plant(s)?
   - Will the supplier be forced to sub-contract portions of large awards?
4. Trade References
   - What other local or foreign public procurement programs and hospitals buy from the supplier?
   - How long has the supplier served the above groups?
   - What is the experience of these customers with regard to the supplier's quality and service?
5. Financial Status
   - Is the supplier financially stable?
   - Will the supplier remain in existence for the entire contract period?
6. Corporate Associations
   - Is the supplier a subsidiary, a parent company, or in some other way formally associated with known suppliers? If so, what is the reliability of the known supplier?
   - Is the supplier producing certain products under a supervised licensing agreement with a known supplier?
7. Reputation
   - How is the supplier regarded by knowledgeable physicians and pharmacists?
   - Is any information available from public sources (newspaper, trade journals, etc.) concerning the supplier's performance in other countries?

a. Evaluating New Suppliers

For both purchasing officers developing new procurement systems, and those operating well-established systems, there are at least three ways of evaluating potential new suppliers: (1) informal information gathering, (2) test purchase, and (3) formal registration. Figure III.C.2. summarizes the questions which must be answered in the evaluation of new suppliers. The following chapter, Chapter III.D., deals with many of the technical aspects of quality assurance.

Informal Information Gathering -- Informal information gathering is currently the most common method used by public purchasing programs in developing countries to assess new suppliers. It is also the least expensive and least time-consuming method. It relies on the opinions and experiences of pharmacists, physicians, and other individuals.

The difficulty with informal information gathering is that opinion is highly subjective and open to bias. The purchaser risks losing a low-cost, reliable supplier because of outdated or unsubstantiated negative information about that supplier or because of positive information about a more expensive supplier in the face of no available information about the low-cost supplier. In addition, opinions can easily be influenced by opportunities for personal gain. Also, there is a tendency to ignore totally unknown suppliers, some of whom might have provided high quality drugs inexpensively.

Informal methods can be improved by structuring opinions according to the Checklist in Figure III.C.2. and recording the opinions in writing.

Test Purchases -- Some countries assess new suppliers by accepting offers from them when the price and terms are favorable in comparison to known suppliers. The new supplier's service and the quality of his product are then observed carefully during the first few years' business. Products for which high quality or timely delivery are critical are not purchased from new suppliers. For example, an unknown supplier might be awarded a contract for aspirin or Vitamin B complex, but not for digoxin or benzylpenicillin. In practice, test purchasing is rarely used as the sole means to assess a new supplier; it is generally used in conjunction with informal information gathering.

Formal Registration -- Formal registration is the most objective, the most thorough, and the most effective means to evaluate new or unknown suppliers. Unfortunately, it is also the most lengthy method and the method most likely to dissuade new suppliers.

Figure III.C.2. indicates the information a purchaser should attempt to ascertain through the formal registration process. Appendix III.C.4. contains samples of a registration form recently introduced by the State Pharmaceutical Corporation of Sri Lanka and one used by a well-established procurement service for a group of independent hospitals in the United States.

Although the entire process of registering an individual supplier may take many months and require letters from banks and other buyers, it should involve little staff time. The supplier must take the initiative in filling out the registration form and, wherever possible, the supplier should be asked

to make the arrangements for additional reports. Although all this "paperwork" may dissuade some suppliers, experienced suppliers have often prepared these forms in the past and are quickly able to collect the required information. If a local agent is involved, the very process of completing registration may provide useful information on the reliability of the agent and his relationship with the primary supplier.

b. Monitoring Supplier Performance

Once a supplier has started doing business with the purchaser, the purchaser has the opportunity to monitor the supplier's reliability with regard to service and quality. The supplier's performance then becomes the basis for decisions regarding future purchases from that supplier. As with the selection of new suppliers, the monitoring of supplier performance is often done informally and without written records. However, experienced professional purchasers generally prefer a formal monitoring system. The advantages of such a system are noted below.

- Formal monitoring makes the selection process more objective, decreasing questionable influences on purchasing decisions, and rewarding reliable, though perhaps unfamiliar, suppliers.

- By recording information on delivery times it allows the purchasing staff to anticipate delays and late deliveries and to make appropriate schedule adjustments.

- It allows the purchasing staff to eliminate from consideration suppliers whose performance is unacceptably unreliable.

- A written monitoring system is independent of current staff; the experiences of personnel who retire, are transferred, or leave the purchasing staff for some other reason are not lost, but remain in the supplier's permanent record.

- Since the monitoring system will influence future purchasing, its existence may encourage feedback from the field regarding poor packaging, deterioration, or other sources of losses which may not be blatant enough to come to the purchasing office's attention with an informal system.

- A well-organized performance record allows the purchasing staff to calculate the hidden costs resulting from late deliveries, poor packaging, omission of documents, and other supplier errors which add to the ultimate cost of a product (see Appendix III.C.1.).

The monitoring system should include both a supplier file and a product file.

Supplier File -- If registration of suppliers is required, the supplier file should include copies of all registration papers and references. In addition, any special correspondence, complaints, and other anecdotal informati about suppliers should be filed there. The information of particular importanc in assessing service and quality performance appears in Figure III.C.3.

Figure III.C.3.

Monitoring Supplier Performance

Service Component

1. Participation Record

   - Does supplier attempt to alter or withdraw bids after submitting them?
   - Does supplier accept an award of a bid and ultimately fail to deliver the product?

2. Response to Inquiries

   - Does supplier adequately respond to all inquiries from the purchaser within a reasonable period of time?
   - Does supplier provide information regarding the status of outstanding orders?

3. Delivery Time

   - What is the supplier's average promised lead time?
   - What percent of shipments are late? How many days (weeks, months) late?

4. Adherence to Delivery Instructions

   - Do shipments arrive under the proper shipping conditions (e.g., cold storage for vaccines)?
   - Do shipments arrive at the correct port?
   - Does supplier send divided shipments as requested (e.g., split deliveries)?

5. Provision of Documents

   - Do shipments arrive with all required documents correctly and completely filled out and signed?
   - If required documents are omitted, does the supplier send the correct documents as quickly as possible?

6. Packing and Labeling

   - Does supplier ship the correct dosage form? Correct package size? Correct quantity? Are short-shipments frequent?
   - Is labeling complete and adequate for proper use? Is it in the correct language?

7. Expiring Products Policy

   - Does supplier allow the return for credit or exchange of products nearing (e.g., within 3 months of) their eppiration date?
   - Does supplier perform analyses on samples of products approaching their expiration date to determine whether longer shelf-lives can be applied to the products? Is there a charge?
   - Does the supplier send drugs with unreasonably short expiry dates?

8. Cost Improvement Suggestions

   - Does supplier make suggestions concerning ways in which the purchaser can reduce costs (e.g., by combining or splitting orders, altering delivery schedules)?

Quality Component

1. Pharmaceutical Product

   - Does the product conform to specified pharmacopeial standards with regard to identity, purity, potency, physical appearance, dissolution, etc.?
   - Does the supplier provide reliable quality control analysis results?
   - Does the supplier cooperate in making samples available and paying for quality control tests performed by independent quality assurance agencies?
   - Do the products last throughout the period of their stated shelf-life? Do they disintegrate?

2. Packaging Materials

   - Is export packaging sufficiently rugged to assure arrival in the country in good condition?
   - Does the external packaging protect the product from damage during transport within the country (e.g., are vials sufficiently padded to withstand long trips on extremely rough roads)?
   - Is the immediate container able to withstand rough in-country transportation, heat, and humidity (e.g., will pressure-sealed lids on tins shake loose on rocky roads)?

The clerical expense of detailed information collection for all suppliers may outweigh the value of the information if the number of orders and number of suppliers is large. However, a data collection form and data procedures should be devised for "Significant Suppliers". These are the suppliers who provide items of critical medical importance and the suppliers who account for the greatest proportion of the purchase funds. For most programs, only about 10 percent of the entire supplier group would be considered "Significant Suppliers". By concentrating on monitoring these suppliers, the purchasing staff can be used most efficiently.

The information collected in the supplier file can be used (1) to estimate lead times -- an important task in preventing stockouts and establishing buffer stocks, (2) to calculate hidden costs when selecting a supplier, (3) to establish a merit rating for each supplier, and (4) to aid in expediting the receipt of goods once a supplier has been selected. Although many hidden expenses can be reduced by enforcement of contract terms and some can be reimbursed from performance bonds, the medical risk from stockouts and the administrative expense of correcting supplier errors make it desirable to uncover and avoid suppliers with high hidden costs.

Figure III.C.4.

A Supplier Merit Rating System

Performance Measure	Maximum Points
Service Component	
1. Participation Record	4
2. Response to Inquiries	4
3. Delivery Time	10
4. Adherence to Delivery Instructions	6
5. Provision of Documents	4
6. Packing and Labeling	6
7. Expiring Products Policy	4
8. Cost Improvement Suggestions	6
Quality Component	
1. Pharmaceutical Product	40
2. Packaging Materials	16
Total Possible Points	100

Adapted from Bailey, 1978.

Merit rating systems vary considerably in their complexity from those which simply rate suppliers on a numerical scale from one to ten to those which rank suppliers on the basis of statistical probabilities derived from precise quantification of past performance. Figure III.C.4. presents the outline for a simple 100-point system based on the performance measures listed in Figure III.C.3. This system is adapted from one used by a commercial firm to monitor the 200 suppliers (out of 1200 to 1500 regular suppliers) who provide 80 to 90 percent of the firm's materials and equipment. To operate such a system, information must be collected and organized by the categories listed in Figure III.C.3. and an objective system for assigned performance points must be devised.

Neither the process for calculating the expected hidden cost for suppliers (Appendix III.C.1.) nor the operation of a merit rating system (Figure III.C.4.) is inherently time-consuming or expensive; both do require a skilled professional manager or management consultant and competent clerical staff. Nevertheless, the principles of monitoring supplier performance can be incorporated into a monitoring system by any purchaser, regardless of staff availability or competence.

Product File -- Product files are used to record the standard technical specifications used in purchasing a specific item and to record the performance of past suppliers of the product. Detailed product records are particularly important with products for which quality is of special importance. Products for which bioavailability is a consideration (see Appendix III.D.1. in Chapter III.D.) and products for which keeping properties are especially important should have their own product file. Product files should facilitate contract preparations as well as supplier selection. A sample product card is shown in Figure III.C.5.

4. SELECTING SUPPLIERS

In many countries the responsibility for selecting suppliers for government programs and the criteria for selection are specified by law and difficult to change. However, where they are not specified or where change in the law is possible, several options are available. These options will be reviewed briefly.

a. Decision-Making Authority

In assigning the ultimate authority for selection of suppliers to a specific individual or committee, several factors are considered, including the following:

Technical Expertise -- The decision-maker must possess or have access to the technical expertise necessary to evaluate arguments concerning pharmaceutial quality and substitutability. Therefore, pharmacists and physicians knowledgeable in clinical pharmacology must be actively involved as decision-makers or consultants.

Figure III.C.5.

Sample Product Card

Side One—Product Specifications

Generic Name:	Category:	
Trade Names:		Code Number:
Form:	Dosage:	Package Size:
Acceptable Pharmacopoeial Standards:		
Additional Technical Specifications:		

Side Two—Supplier History

Purchase Order Number	Supplier	Quantity	Unit Price	Date Promised	Date Delivered	Comments

Ability to Act Promptly -- The assignment of decision-making authority should be such that the selection process is not unduly prolonged. One reason for using direct or negotiated purchasing for pharmaceuticals is to shorten the lead time. This advantage is lost if the process for issuing indents or purchase orders is lengthy. Thus, for most direct and negotiated purchases, the contracting authority should rest with the purchasing manager or an equivalent officer.

Integrity -- The assignment of decision-making authority should reduce or minimize the chance for special "commissions" or other opportunities for personal gain to influence the selection process. For this reason tenders and large direct purchases must generally be approved by a committee. In addition, when the lowest bidder is not awarded the contract, the reasons for this decision should be documented.

For direct or negotiated purchases, where the purchasing authority frequently rests with a single individual, that individual should be someone with technical expertise, preferably a pharmacist. In countries where pharmacists have not routinely been involved in purchasing decisions, purchasing inefficiencies have frequently been found.

Depending on the value of the purchase, the participation of more than one individual in the final selection is sometimes required. Country Study III.C.1. illustrates how this principle is applied in one Central Asian country. Authority for the selection of suppliers for tender purchases often

Country Study III.C.1.

Procurement Authority in Central Asia

For domestic purchases other than those from the government drug importation monopoly, purchasing officers are authorized to obtain drugs through the following procdures, as specified by the Ministry of Justice Purchasing Regulations:

(1) Purchases up to U.S.$250: The President of Administration, Deputy Minister or Minister designates one man to make inquiries and make the purchase. In so doing, the designee must prepare a Price Comparison for Minor Purchases form.

(2) Purchases from U.S.$250 to $1250: The regulations are identical to (1) above, except that two persons must agree on the purchase.

(3) Purchases from U.S.$1250 to $2500: The regulations are identical to (1) above, except that three persons must agree on the purchase.

(4) Purchases of U.S.$2500 and over: In these cases, the purchase must be advertised for two months, and then a committee chaired by the Minister will make the selection.

rests with one or more committees. Although no objective evidence is available, it is our impression that large tender boards with diverse representation afford more protection from the influence of special interests on purchasing decisions. Country Study III.C.2. provides a sampling of tender board composition in public drug programs.

A final point is that the composition of tender boards may influence the credibility of the public procurement system. In many countries physicians' groups have taken skeptical or opposing positions to public procurement programs. Participation of representatives of these groups in supplier selection can help build support among the physicians.

b. Selection Criteria

The first step is the preparation of a comparison chart (Figure III.C.6.) listing each supplier, the quoted price in a standard currency, payment terms, promised delivery date, and comments regarding supplier quality and service.

Country Study III.C.2.

Tender Boards in Selected Countries

Costa Rica -- Ministry of Health tenders are awarded by the Pharmacy Committee, which consists of two physicians, two pharmacists (including the official Ministry of Health pharmacist), the head of purchasing for the Ministry, the head of supplies for the Ministry, and the head of General Inventories. (1978)

Malaysia -- Authority rests with the Ministry of Health Tender Board, which consists of the Director General of Health (an elected official), the Secretary General of Health (a civil service employee), a representative from the Ministry of Finance, and a representative from the Ministry of Trade and Finance. The Board is advised by the Director of the Ministry's Pharmacy Division and the Chief of the State Pharmaceutical Laboratories and Store. (1978)

Papua New Guinea -- The Papua New Guinea (PNG) Office in Sydney, Australia is the main purchasing office for the country. For all tenders, a contract clerk in the PNG office prepares a comparison sheet of the prices for each offer and available information on quality. Following established guidelines, the clerk recommends a supplier. That recommendation is reviewed by an experienced purchasing officer and then presented to the Tender Board, which consists of the PNG Consul (a diplomat) and the Director and Assistant Director of the PNG Office (both professional purchasers). Tenders for items up to U.S.$115,000 can be awarded by the Office Tender Board. When necessary, the Board is advised by a nurse in the Office who has extensive experience in drug procurement and by the Chief of Pharmaceutical Services in PNG, a pharmacist. Tenders for items over $115,000 are referred back to the Central Tender Board in Port Moresby, PNG. (1978)

Peru -- In the Basic Medicines Program, a Technical Committee, consisting of 4 pharmacists from the Health Departments of the Armed Forces (one each from Navy, Police, Air Force, and Army) and 3 physicians from the Ministry of Health, recommends a specific supplier for each tender item. The Committee considers quality first and cost second. The Economic Board, chaired by the Minister of Health, reviews the recommendations of the Technical committee and makes the final decision. In contrast to the Technical Committee, the Economic Board places great emphasis on price. In about 80% of the cases, the Economic Board approves the Technical Committee recommendation. In the remaining 20%, the Board selects another supplier.

Sri Lanka -- The State Pharmaceuticals Corporation is the importer for all public sector purchases and the majority of private sector purchases. The tender board consists of the Chairman, Managing Director, and one other Director of the State Pharmaceuticals Corporation, and two Professors of Pharmacology. For private sector purchases, one representative each from the Sri Lanka Medical Association (SLMA) and the Independent Medical Practitioners Association (IMPA) are present as advisers. For public sector purchases, the Deputy Director of Medical Services and the Assistant Director Medical Supplies replace the representative of the SLMA and IMPA. (1978)

Figure III. C. 6.

Schedule of Tenders

Item Number: ______________________

Product: ______________________

MINISTRY OF HEALTH

Department of Medical Supply

Tender Number: ______________________

Closing Date: ______________________

Name and Address of Tenderer	Local Agent	Pharmacopeial Standard Offered	Delivery Dates Promised		Unit Prices					Terms of Payment (Discounts)	Offer Valid Until	Samples			Quality Certificate	Supplier Reliability	Remarks (include deviations from contract specifications)
			First Shipment	Other Shipments	FOB	C & F		CIF				Requested	Received	Tested			
					Foreign Currency	Foreign	Local	Foreign	Local								

Additional information such as country of origin and willingness to provide split deliveries should be included where necessary. Before placing a supplier on the comparison chart, the responsible clerk should determine that the supplier has completed the registration process if there is one, and that he has agreed to adhere to all specifications required for the product. If the supplier's offer deviates from the stated specifications (e.g., 250 mg. ferrous sulfate, rather than 300 mg.), it should be reviewed by a technical officer or technical committee to determine whether the alteration is acceptable

Once a comparison chart of acceptable suppliers is prepared, the purchasing manager or tender board can then select a supplier. There are routine criteria which are applied to all decisions, and special criteria, which may apply in only certain circumstances (Figure III.C.7.).

Routine Criteria -- Usually the objective of supplier selection is to choose the supplier who offers the lowest total or ultimate cost with acceptable quality. The approach commonly used by professional purchasers is to begin with the lowest total cost and eliminate suppliers whose quality does not meet required standards.

The total or ultimate cost is the sum of both the visible costs and the hidden costs associated with service and quality performance (see Figure III.B.1. in Chapter III.B.). The visible costs include the sum of the cost of goods, insurance, freight, terms cost (i.e., the cost related to the payment terms), and other specific costs which are known at the time of purchase.

Since public procurement programs generally accept the same trade and payment terms from all suppliers, the quoted prices are an adequate means of comparing visible costs. However, if some suppliers offer terms other than letter of credit (e.g., deferred payment), the "terms cost" may make a substant difference and should be included in the calculation of total visible cost.

If both local and foreign suppliers are bidding, there is more likely to be a difference in trade terms. Local suppliers will often bid on Delivered to Purchaser's Warehouse terms, while the foreign supplier bids on C.I.F. (cost, insurance, freight) terms, purchaser's main port. To make these two prices comparable, the purchaser must add to the foreign supplier's C.I.F. price all duties, fees, and handling costs to the purchaser's warehouse.

The hidden costs resulting from the quality and service performance of the supplier can be calculated in monetary terms and used in conjunction with the visible costs to compare the total costs for each supplier (see Appendix III.C.1.). A simpler alternative means of including past performance in the selection process is to provide a summary of information from the supplier file in the form of comments on the bid comparison chart.

Wherever possible, delivery dates should be compared in terms of expected delivery date (see Appendix III.C.2.), rather than promised delivery date. If the lowest acceptable bidder's expected delivery date is beyond the required delivery date, then the effect of a shortage of the particular drug must be considered in light of the cost of alternative treatments or the cost of a special air shipment to cover the interim period.

Figure III.C.7.

Supplier Selection Criteria

A. Routine Criteria	B. Special Criteria
(1) Visible Costs	(1) Local Preference
(2) Quality Reliability	(2) Supplier Balance
(3) Service Reliability	(3) Intergovernmental Trade Agreements
(4) Promised Delivery Date	(4) Donor Agency Restrictions
(5) Compliance with Product Specifications	

Special Criteria -- In addition to the routine criteria, special criteria are sometimes applied to the purchasing decisions (Figure III.C.7.). Government-mandated preference may be given to local firms to stimulate the industry. Domestic manufacturers have a certain natural advantage in terms of reduced freight costs and, often, import duty exemption. The purchasing process can give them a further advantage by adding a certain percentage to the value of the foreign bid as a final mathematical step in the bid evaluation process. The local price is then compared with the upwardly adjusted foreign price. While allowance for higher prices is the standard means of granting local preference, some countries have also granted local preference by accepting lower standards of quality from local manufacturers. Although new manufacturers in any industry are subject to difficulties in quality control, acceptance of lower quality in public procurement programs may result in a decline in the program's public credibility and physician support.

Supplier balance refers to the geographic and political distribution of suppliers which the buyer may want in order to protect himself from the loss of a major supply area or trade route as a result of war or international political forces. This would mean, for example, that antibiotics would not all be purchased from a single Eastern European country or all cardiac medications from Switzerland.

Intergovernmental trade agreements may facilitate, encourage, or require procurement from specific countries. Some donor agencies, particularly bilateral aid programs, restrict the range of sources for drugs bought with their funds. By limiting the range of suppliers both of these constraints have the potential to increase costs. Some trade agreements provide for special lines of credit and facilitate the issuing of import licenses.

5. PURCHASING THROUGH LOCAL AGENTS

Foreign manufacturers and exporters are commonly represented in developing countries by local importers or representatives. The decision to require, to merely encourage, or to avoid buying through local agents will affect the range of foreign suppliers doing business with the buyer, the efficiency of

Figure III.C.8.

Advantages and Disadvantages of Buying Through Local Agents

ADVANTAGES

1. Speeds and improves communication -- Local agents may be authorized to make certain decisions without a special contact with the foreign supplier. Where communication with the foreign supplier is necessary, the local agent is better able to contact the appropriate person at the foreign supplier's office.

2. Locates least expensive acceptable supplies -- Where the public program purchases through tenders or negotiated prices from multiple sources, it is in the interest of the local agents to locate inexpensive suppliers. Agents can sometimes locate sources which might not otherwise have come to the attention of the purchaser.

3. Facilitates payment -- Local agents can sometimes enable the government to make all payments in local currency and allow deferred payment. Currency conversions are a troublesome part of the payment process and some countries specify that all payments will be made in local currency to local agents.

4. Expedites delivery -- Local agents often handle port-clearing. When illicit commissions are required to move drugs through the port, local agents are better able to pay these fees and, by saving time, save the government money.

5. Speeds receipt of emergency supplies -- In many countries local agents maintain stocks within the country, which speeds the receipt of emergency supplies and may reduce the amount of warehouse space required by the purchaser.

6. Affords greater legal recourse -- The presence of an in-country agent affords the purchaser greater opportunity for legal action if the supplier defaults in terms of quality, delivery time, or adherence to other specifications.

7. Introduces new products -- Occasionally, new products or formulations are introduced which are indeed cost-effective alternatives to existing products. The agent is necessarily biased, but he may provide scientific articles in support of the product. Other information sources should be sought to supplement the introductory information provided by the agent.

DISADVANTAGES

1. May slow and confuse communication -- If a local agent is untrained, unmotivated, poorly supervised, or works only part-time, he may actually lengthen and confuse arrangements with the foreign supplier.

2. May increase cost -- Use of local agents may effectively add as much as 15 to 30 percent to the visible cost, even though their commission is often much less than this.

3. Serves as a source of blackmarket drugs -- In some countries, the licensed importers are a major source of drugs for illicit uses. The use of local agents brings with it the need to regulate their activities through licensure, regular inspection of records, and other activities.

4. May completely default on an order -- In situations where local agents are not financially stable, governments occasionally find that agents have gone out of business and disappeared after the government has placed an order.

5. Attempts to increase drug consumption -- With their commissions, local agents employ detailmen or company representatives to visit local physicians to advocate the use of products recently bought from them and to encourage physicians to request new drugs.

communication between the buyer and the supplier, the choice of trade and payment terms, and other factors in the procurement process.

Major advantages and disadvantages of buying through local agents are listed in Figure III.C.8. In summary, the establishment of a policy with regard to the involvement of local agents in purchasing will depend on the purchaser's level of expertise and knowledge of drug markets, the means of communication available to the purchaser, the warehousing and wharf clearing capabilities of the purchaser vis-a-vis the current or potential agents, and the nature of blackmarket and illicit drug traffic.

Some of the negative aspects of purchasing through local agents may be avoided through licensing requirements, specifications for standards of recordkeeping and storage facilities, regulations to assure adequate security, limitations on allowable commissions, restrictions on the activities of company representatives, and the establishment of a control agency for local agents. At the same time, purchasing through local agents substantially increases the level of personal contact and its advantages may be impressive enough to warrant encouraging the establishment of local agencies.

SUMMARY

Careful selection of suppliers is important because it can affect both the quality and cost of drugs acquired.

Supply sources include:
- Primary sources (those engaged in manufacture themselves)
  (1) government production
  (2) local private manufacturers
  (3) foreign manufacturers
- Secondary sources (those who do not manufacture pharmaceuticals, but obtain them from an independent producer)
  (1) donors
  (2) international procurement services
  (3) independent foreign exporters

A wide range of suppliers increases potential for (1) lower prices, (2) more reliable suppliers, (3) obtaining necessary, but unusual, drugs or dosage forms, (4) the availability of emergency supplies.

Bids can be attracted from potential suppliers through various means, including direct inquiries and advertisement of public tenders.

An effective procurement staff must develop a system of determining supplier reliability and eliminating those suppliers whose performance is clearly substandard. New suppliers can be evaluated through:
(1) informal information gathering
(2) test purchases
(3) formal registration (the most objective, the most thorough, and the most effective, but may dissuade new suppliers).

Once in business, supplier performance should be formally monitored with both a supplier file and a product file.

The individual or committee with the ultimate authority for selecting suppliers should have technical expertise, be able to act promptly, and be trustworthy.

Selection of a suppler for a particular order should be made by comparing acceptable suppliers. Wherever possible, specific selection criteria should be adopted and utilized.

Foreign suppliers are often represented in developing countries by local agents. The advantages and disadvantages of purchasing through local agents should be considered, as a procurement office establishes a policy with regard to their involvement.

CHAPTER III.C. REFERENCES

Bailey, P.J.H.: Purchasing and Supply Management, 4th Edition. London: Chapman and Hall, 1978.

Combs, P.H.: Handbook of International Purchasing, 2nd Edition. Boston: Cahners Publishing Co., Inc., 1976.

Gasdia, S.D. and Brennan, E.C.: Purchasing Pharmaceuticals on a Competitive Basis. Hospital Formulary Management, August-September, 1968.

Kudrna, D.A.: Purchasing Manager's Decision Handbook, Boston: Cahners Publishing Co., Inc. 1975.

Appendix III.C.1.

Calculating Hidden Cost Ratios

The total cost of purchasing an item from a specific supplier is the sum of the quoted price (usually based on C.I.F. terms) and any hidden costs. In comparing quotations from different suppliers, professional procurement officers sometimes find it advantageous to calculate the expected hidden costs for each supplier, based on his past performance. With this information, the Hidden Cost Ratio for each supplier can be calculated. The Hidden Cost Ratio is the sum of all hidden costs incurred in past orders divided by the sum of the visible costs for all past orders:

$$\text{Hidden Cost Ratio} = \frac{\text{Hidden Costs}}{\text{Visible Costs}}$$

Visible Costs = Sum of prices, insurance, freight (C.I.F.) for all past orders.

Hidden Costs = Commission for Local Agents

+ Cost of Late Deliveries (include air freight for emergency needs, use of more expensive alternatives, higher cost for emergency replacements, etc.)

+ Cost of Delivery Errors (sum of costs incurred because of short-shipments, incorrect drugs shipped, shipments delivered to wrong port, additional port costs because proper documents have not been supplied, etc.)

+ Value of Losses Due to Poor Packaging

+ Replacement Cost of Unusable Drugs (short shelf-lives, disintegrated drugs, etc.)

- Value of Cost-Saving Contributions (deferred payment terms, suggestions for less expensive dosage forms, etc.)

For example, assume that Supplier A has sold the government U.S.$100,000. worth of drugs in the past (Visible Cost = $100,000.). A review of the procurement office Supplier File might show that for these purchases, the following hidden costs were incurred:

(1) Commission for Local Agents (3%) = $3000.

(2) Late Deliveries (air freight and higher price for temporary emergency stocks) = $9000.

(3) Delivery Errors (2% average short-packing) = $2000.

(4) Losses from Poor Packaging (losses not covered by insurance) = $2500.

(5) Unusable Drugs (replacement cost for tablets which disintegrated in transit; expired products not replaced by supplier) = $5000.

(6) Cost-Saving Contributions (discount achieved because of Supplier A's suggestion of alternative dose forms for a few common items) = $1500.

Based on this experience with Supplier A, the procurement office calculates the following Hidden Cost Ratio:

$$\text{Hidden Cost Ratio} = \frac{\$3000. + \$9000. + \$2000. + \$2500. + \$5000. - \$1500.}{\$100,000}$$

$$= 20\%$$

This information can then be used to estimate total costs of later orders. A Hidden Cost Ratio of 20% for Supplier A means that the total cost for the drug supply system will be about $1.20 for every $1.00 quoted by Supplier A for a product. For example, if Supplier A quotes a price of $100. for an item, and Supplier B quotes a price of $90. and has a Hidden Cost Ratio of 50%, Supplier A would have the lowest expected total cost ($120. for Supplier A versus $135. for Supplier B).

In practice, it is often difficult to collect the necessary information for calculating Hidden Cost Ratios. Once this information is collected, it can quickly become outdated if suppliers undergo a substantial improvement in their performance. Furthermore, the system is of no use in comparing previous suppliers with entirely new suppliers. Nevertheless, some system for recording past experiences with suppliers should be used in order to avoid contracting with suppliers whose consistently poor performance leads to extremely high hidden costs.

Appendix III.C.2.

Calculating Expected Delivery Dates

Wherever possible, delivery dates should be compared in terms of the expected delivery dates, rather than promised delivery dates. In other words, the supplier's past rate of late delivery and the average number of days late should be used to calculate the expected delivery date from the promised delivery date. The calculation is made as follows:

$$DD_E = DD_P + ((OD)(\%OD))$$

Where:

DD_E = expected delivery date

DD_P = promised delivery date

OD = average overdue period in days

% OD = percentage of orders overdue

If the lowest acceptable bidder's expected delivery date is beyond the required delivery date, then the effect of a shoratage of the particular drug must be considered. The cost of alternative treatments and the cost of a special air shipment to cover the interim period must be considered.

Obviously, calculation of the expected delivery date requires that complete, accurate supplier files be kept. Although time consuming, such files are invaluable in avoiding costly late deliveries.

Appendix III.C.3.

Organizations and Information Sources for Locating Pharmaceutical Suppliers

a. International Procurement Services -- See text (p.152) for a general description of these services.

Afro-American Purchasing Center
One World Trade Center
New York, NY 10048 U.S.A.

Crown Agents
4 Millbank Westminster
London SW1P 3JD England
CABLE: CROWN LONDON SW1

ECHO
5 Robin Hood Lane
Sutton, Surrey SM1 2SW, England
CABLE: ECHO SUTTON

International Dispensary Association (I.D.A.)
P.O. Box 3098
1003 AB Amsterdam, The Netherlands
CABLE: IDAHQ

Lifeline Relief and Development
Services International, Ltd.
Unit F, Southampton Airport
P.O. Box 56938
Nairobi, Kenya

Pan American Health Organization
525 23rd Street, N.W.
Washington, D.C. 20037 U.S.A.

UNICEF
Supply Division
866 United Nations Plaza
Sixth Floor
Room A 6114
New York, NY 10017 U.S.A.
CABLE: UNICEF, NEW YORK

United Nations Fund for
Population Activities
485 Lexington Avenue
New York, NY 10017 U.S.A.

World Health Organization
Drug Policies and Management
1211 - Geneva 27
Switzerland
CABLE: UNISANTE, GENEVA

b. Directories of Pharmaceutical Manufacturers

Surgical Trade Buyers Guide. 40th Edition. New Jersey: Surgical Business Publishers, 1979-1980.
Standard work covering manufacturers of medical and surgical supplies and equipment. A product section with an alphabetic listing of equipment and supplies, list of manufacturer's representatives, etc.

World Directory of Pharmaceutical Manufacturers, Second Edition, 1978. IMSWORLD Publications Ltd., 229/231 High Holborn, London WC1V 7DA, England.
Alphabetical listing of major firms in the 34 principal producing countries, excluding centrally planned economies. Listings include a general description of the companies, names of executives, and principal products. Brief directories are included for Asia, Africa and the Middle East, the Caribbean, Central and South America, and Scandinavia. (Approximate cost, U.S.$130.00).

World Pharmaceutical Firms, 1972. Noyes Data Corporation, Park Ridge, New Jersey, U.S.A.
Alphabetical listing by country of over 6,000 firms in 52 countries throughout North and South America, Western and Eastern Europe, Africa, the Middle East, Asia, and Australasia, including national production facilities in centrally planned economics.

c. International and Regional Trade Associations

International Federation of Pharmaceutical Manufacturers Associations (IFPMA), P.O. Box 328, Nordstrasse 15, CH-8035 Zurich, Switzerland, CABLE: PHARMAFED ZURICH

Groupement International de l'Industrie, Pharmaceutique des Pays de la CEE - GIIP (EEC), 49, Square Marie-Louise, B-1040 Bruxelles 4, Belgium, CABLE: FECHIMIE
Grouping of the pharmaceutical industry associations of Belgium, Denmark, France, Federal Republic of Germany, Ireland, Italy, Netherlands, and United Kingdom.

Pharmaceutical Industries Association in the EFTA - PIA, Nordstrasse 15, P.O. Box 328, CH-8035 Zurich, Switzerland, CABLE: PIASSOPHARM
Grouping of the pharmaceutical industry associations of Austria, Finland, Norway, Portugal, Sweden, and Switzerland.

Federación Latinoamericana de la Industria Farmacéutica - FIFARMA, Secretaría Ejecutiva, Carlos Pellegrini 763 8º P, Buenos Aires, Argentina
Grouping of the pharmaceutical industry associations of Argentina, Bolivia, Brazil, Central America, Chile, Colombia, Ecuador, Mexico, Paraguay, Peru, Uruguay, and Venezuela.

d. National Trade Associations Including Exporters in Centrally Planned Economies

Australian Pharmaceutical Manufacturers Association - APMA
45, Macquarie Street
Sydney, NSW 2000, Australia
CABLE: APMASYD

Fachverband der Chemischen Industrie Oesterreichs
Gruppe Pharmazeutika
Bauermmarkt 13, Schliessfach Nr. 69
A-1011 Wien, Oesterreich, Austria
CABLE: CHEMVERBAND

Association Generale de l'Industrie du Medicament - AGIM
49, Square Marie-Louise
B-1040 Brussels, Belgium
CABLE: FECHIMIE

Pharmaceutical Manufacturers Association of Canada - PMAC
141 Laurier Avenue West, Room 1110
Ottawa, Ontario K1P 5J3, Canada

FEDEFARMA - Federacion Centroamericana de Laboratorios Farmaceuticos
6a. Av. "A" 10-38, Zona 9
Ciudad de Guatemala, Guatemala

Chemapol Sopfa
Panska 9, Praha I
Czechoslovakia

MEFA Foreningen af Danske Medicinfabrikker
Landemaerket 25
DK-1119 Copenhagen K, Denmark
CABLE: MEFADEX

Lääketeollisuusyhdistys r.y. (LTY)
Iso Roobertinkatu - 4-6A, P.O. Box 316
SF-00121 Helsinki 12, Finland
CABLE: CHEMAS

Syndicat National de l'Industrie Pharmaceutique
88, rue de la Faisanderie
F-75782 Paris Cedex 16, France

Bundesverband der Pharmazeutischen Industrie
Karlstrasse 21
D-6000 Frankfurt am Main 8
Federal Republic of Germany
CABLE: PHARMINDUSTRIE

The Hong Kong Association of the Pharmaceutical Industry - HKAPI
1609A, Asian House, 1, Hennessy Road
Hong Kong
CABLE: PHARMIND

MEDIMPEX
Hungarian Trading Company for Pharmaceuticals
H-1808 Budapest, 5
P.O. Box 126, Hungary

Employers Syndicate of Pharmaceutical and Hygienical Industries - ESOPHI
312/1 Kakh Avenue
Tehran, Iran

Manufacturers' Association of Israel
Pharmaceutical Section
13, Montefiore Street, P.O. Box 29116
Tel-Aviv 65 164, Israel
CABLE: PALMANUF

Associazione tra Industrie Chimico-farmaceutiche ASSOFARMA
Via G.D. Romagnosi 18/A
I-00196 Roma, Italy

The Federation of Pharmaceutical Manufacturers Association of Japan - FPMAJ
9, Nihonbashi - Honcho 2 chome
Chuo-ku, Tokyo 103, Japan
CABLE: NICHIYAKUREN

Malaysian Pharmaceutical Trade and Manufacturers Association
c/o Essex Asia Ltd.
3rd Floor, Jaya Supermarket
Jalan Semangat
Petaling Jaya, Selangor, Malaysia

NEFARMA - Nederlandse Associatie van de Farmaceutische Industrie
Franciscusdreef 50
NL-2505 Utrecht, The Netherlands

Norges Medisinalindustris Felleskontor - NOMI
Sorligaten 8
Oslo 5, Norway
CABLE: NOMIDIN

CIECH
Warsazawalul, Jasna 12
Skrytha Pocztowo NR. 271,.Poland
CABLE: CIECH WARSZAWA

Singapore Association of Pharmaceutical Industries - SAPI
Secretaries, Goh, Tan and Co.
Shing Kwan House, 11th Floor
4, Shenton Way
P.O. Box 3039 Singapore
CABLE: CERTIFIED

FARMAINDUSTRIA - Servicio Técnico Sindical de la Industria Farmacéutica
Fray Juan Gil, 5
Madrid (2), Spain

Läkemedelsindustriföreningen-LIF
Kungsgatan 32, P.O. Box 1319
S-111 83 Stockholm, Sweden

Swiss Society of Chemical Industries
Nordstrasse 15, P.O. Box 328
CH-8035 Zurich, Switzerland
CABLE: CHIMIESUISSE

Medexport
Moscow, G-200
Smolenskaja-Sennaja, 32/34, U.S.S.R.
CABLE: MEDEXPORT MOSCOW

The Association of the British Pharmaceutical Industry - ABPI
162 Regent Street
London W1R 6DD, England, United Kingdom
CABLE: PHARMIND LONDON W1

Pharmaceutical Manfuacturers Association - PMA
1155 Fifteenth Street, N.W.
Washington, D.C. 20005 U.S.A.
CABLE: PHARM

PLIVA
Pharmaceutical and Chemical Works
Lele Ribra 89 Zagreb, Yugoslavia

Appendix III.C.4.a.

Sample Supplier Registration Form

REGISTRATION OF SUPPLIERS

This Corporation is the monopoly importer of pharmaceutical preparations and the major importer (by value) of pharmaceutical raw materials.

We are maintaining a list of registered suppliers. We are aware that some of you have been registered suppliers to the Department of Health Services, Sri Lanka, and have also supplied the Private Sector and this Corporation. However, in order to maintain a register of suppliers and to have for reference full details of suppliers, we shall be grateful if you could fill this questionnaire, to enable us to consider registering your firm as an approved supplier to this Corporation. Eventually, we will only entertain offers from suppliers registered with the Corporation.

All information will be treated confidentially.

Yours faithfully,

Managing Director.

QUESTIONNAIRE

(Note Separate sheets should be used, where the space provided in this form is inadequate.)

Part 'A' : Commercial

1. Name of Company : .....

2. Address : .....

   P. O. Box No : ..... Telephone : .....

   Cable Address : ..... Telex : .....

3. Year of Establishment .....

4. Form of Company : e. g: Sole Proprietory/Partnership/Limited Company/Trust etc .....

5. Names and Addresses of Parent Companies and/or subsidiaries & Associated Companies, including Overseas Companies :

   .....

   .....

6. Names and Addresses of Branches : .....

   .....

7. Names of International Pharmaceutical Companies with whom you have collaboration agreements and/or joint ventures

   .....

   .....

8. Total Number of Employees : (a) Technical : .....

   (b) Administration : .....

9. **Trade References :** (Give names and addresses, preferably of at least four large overseas customers, to whom reference could be made)

   .....

   .....

   .....

   .....

10. **Financial References :** (Give names and addresses of Bankers together, if necessary, with account numbers. If preferred, sealed Confidential reports, issued by your Bankers could be annexed.)

    .....

    .....

    .....

11. **Capital : Value of** (a) Authorised Capital : .....

    (b) Paid-up Capital : .....

    (c) Reserves : .....

12. **Give total sales turnover in previous three years (give figures for each year separately) split between exports and domestic sales and into the various major operating divisions of your Company :**

    .....

    .....

    .....

13. **Give nett Prodt after taxation for the last three years with approximate rate of growth of your firm per year :**

    .....

    .....

    .....

14. **Give in an annexed list** the names of pharmaceuticals and/or raw materials **actually** manufactured by you, which are available for export. Of these items, please indicate which items are not marketed by you in your country and give reasons why this happens. Your list should give the generic names and respective brand names: annex catalogues, vedemecum etc.

In a separate list you may show the items of pharmaceuticals and/or raw materials manufactured by other firms and which are marketed by you. Please give names of such firms, against the items.

Certificates of Free Sale & Good Manufacturing Practices covering each item you propose exporting should be annexed.

15. Give full details (including value) of exports made to Sri Lanka (Ceylon) previously, either directly or through Export Houses. (Give names of such export merchants).

.....

.....

.....

16. Give names of countries to which your processed drugs and/or raw materials are presently exported to :

.....

.....

.....

PART 'B' . TECHNICAL

1. Give full details enclosing brochures (if available) of Manufacturing Plants. Laboratories etc.

2. Give pharmaceutical production capacity separately into the various categories such as Antibiotic Repacking, Injection of Vials, Injection of Ampoules (1 c.c. to 2 c.c.), Injection of Ampoules (over 5 c.c.), Capsule filling, tablet manufacture, physiological solutions, organic synthetic products, Lyophilizing etc., and also the spare capacity available for servicing export orders

.....

.....

.....

3. If you have research laboratories, **give in annexe** the number of laboratories, and the nature of research being undertaken by them.

4. Give the number of specialised personnel working in research laboratories, excluding Administrative personnel, into the various categories such as Pharmacists, Chemists etc.;

Physicians .....

Pharmacists .....

Chemists .....

Other Specialists .....

TOTAL .....

5. Give number of specialised personnel involved in manufacture of your pharmaceuticals (Excluding Administrative Personnel) into the various categories such as Pharmacists, Chemists etc:

Physicians : .....

Pharmacists .....

Chemists : .....

Other Specialists .....

TOTAL :

6 What are the different tests you carry out before a pharmaceutical processed item is put out on the market: e. g. pharmacological tests stability tests accelerated tests chemical tests biological availability tests. Give full details:

.....

.....

.....

7. Give in separate list the names and full addresses and number of beds of some major hospitals in your country, who use pharmceuticals manufactured by your firm.

8. Please provide certificates issued by your Ministry of Health or official organisation in charge of the Control and inspection of pharmaceutical manufacturing facilities to the effect that your establishment fulfils the requirements of good manufacturing practices and local regulations and explain in detail in an annexure the type of control your government enforces on your establishment and on your products.

CERTIFICATION

I, the undersigned, (full name of the person responsible for the establishment)

.....

.....

hereby declare that all the information given above is true, and I assume full responsibility for this declaration with all consequences which might arise from false or erroneous information.

We hereby certify that the information given is true and that the Establishment concerned fulfils the requirements of the local regulations concerning the manufacturing of Pharmaceuticals.

(a) Certification by the Ministry of Public Health or the Official Organisation in charge of the Control and Inspection of pharmaceutical manufacturing facilities

(b) **Certification by the Chamber of Commerce or similar Organisation.**

Appendix III.C.4.b.

Sample Supplier Registration Form

CENTRAL PHARMACEUTICAL SERVICES
MOUNTAIN REGIONAL HOSPITALS
U.S.A.

APPLICATION TO BE A PHARMACEUTICAL VENDOR

Mountain Regional Hospitals purchases pharmaceuticals only from those firms which appear on its "Approved Vendors List". The full and accurate completion of this application is the first step in the process of a firm being placed on our approved list. Other steps include submission of price quotations, review of scientific data supplied by the firm on its products and, at the discretion of the Director of Central Pharmaceutical Services, an inspection of the firm's manufacturing facilities by representatives of Mountain Regional Hospitals. Failure to adequately complete this application will result in it being returned to the firm. No further consideration can be given to a firm pending the acceptance of this application by the Director of Central Pharmaceutical Services.

I. BUSINESS INFORMATION

1. Business name and address of applicant:

2. Address to which bid forms are to be mailed:

3. Type of organization: ☐ Individual ☐ Partnership ☐ Corporation

4. Name of parent company (include brief summary of ownership relation):

5. Name(s) of affiliated concern(s) - include address(es) and summary of relationship:

6. If corporated, indicate state(s):

7. Names of officers, members or owners of concern:
   a. President
   b. Vice-President
   c. Secretary
   d. Treasurer
   e. Others

8. Names and titles of individuals authorized to sign bids in firm's name:

9. Names and titles of individuals to contact on matters concerning bids:

10. Total number of personnel employed:

11. Floor space (square feet) for the following areas:
    Manufacturing
    Quality Control
    Warehouse

12. Indicate pharmaceuticals on which you desire to bid by attaching a supplemental list of current company catalogue.

II. GENERAL INFORMATION

1. Is a registered pharmacist employed by your firm? ☐ Yes ☐ No
   If yes, in what capacities?

   If a registered pharmacist is not employed in the production, formulation, labeling or mixing operation, list the names of the persons personally supervising these operations and attach a detailed resume of their scientific and technical training and/or experience.

2. What state agency is responsible for inspecting and licensing your facilities and operations?

   Date of last inspection:
   Date, number and expiration date of current state license or permit:

3. List current F.D.A. registration information:

4. Number of F.D.A. approved N.D.A.'s held by company:
   List examples of such products:

5. Number of F.D.A. approved antibiotic certifications held by company:
   List examples of such products:

6. List several local, state or federal agencies currently purchasing your products and include length of time doing business with each.

7. If you have not done business with any governmental agencies (or in addition to the above if you choose) list at least five other current customers:

8. List all product recalls (either by F.D.A. or firm) during the last three years and include date of recall and reason for recall:

III. MANUFACTURING INFORMATION

1. Are products actually manufactured or are they repackaged?

2. If any products are repackaged, attach a list of such products showing the name and address of the manufacturer for each product.

3. Are master formula control cards used for manufacturing?
Attach sample form.

4. List the name and address of several companies from which you purchase raw materials:

5. Are measurements and weights of ingredients of each batch double checked?
By whom?

6. Are final yields or volumes checked against theory?

IV. QUALITY CONTROL INFORMATION

1. Do you maintain your own quality control laboratory?

2. List names and addresses of quality control laboratories used in addition to or in lieu of your own laboratory:

3. Are all raw materials completely tested prior to use?

4. Are all finished products tested and released by quality control before release for sale?

5. Are control tests made during production?
List examples:

6. Is bio-availability a part of the quality control testing procedure?

7. If yes, list products so tested and attach reports if F.D.A. approved.

8. Are control samples of each lot retained?
Time retained:

9. Explain in detail procedures for disposition of rejected batches:

V. HOUSEKEEPING AND SANITATION INFORMATION

1. Are all parts of the plant insect and rodent proof?

2. Is the plant fully air conditioned?
List areas not air conditioned, if any:

3. Indicate procedures for cleaning manufacturing and packaging equipment:

4. Are floors, ceilings and walls of such construction as to be easily cleaned?

VI. CERTIFICATION

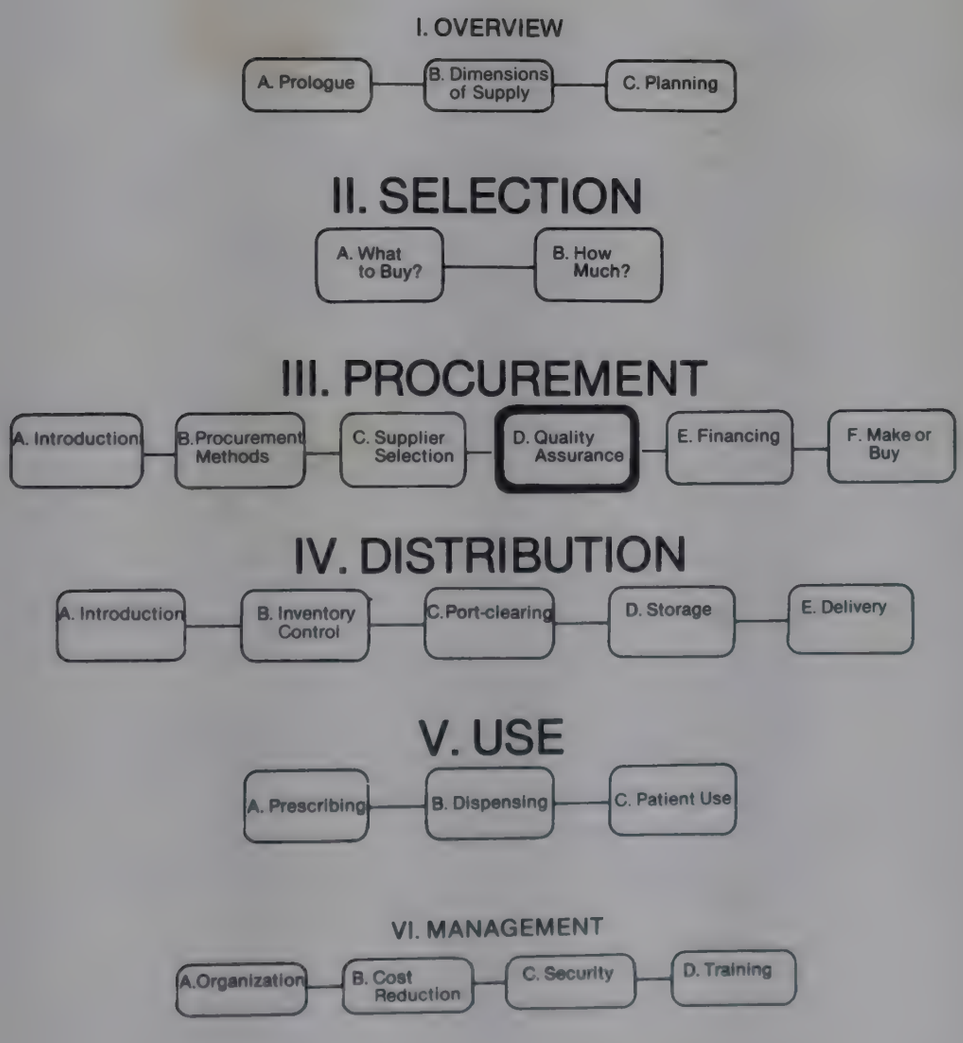
I hereby certify that the information contained herein is complete and correct and that I will cooperate with any official of Mountain Regional Hospitals in making a personal inspection of manufacturing facilities and records.

Signature

Name
Title
Date

Chapter III.D.

How Good are the Drugs: Quality Assurance



	Page
1. DRUG QUALITY	181
a. What is "Drug Quality"?	183
Identity Purity Potency Uniformity Bioavailability	
b. What Determines Drug Quality?	184
c. Why Worry about Drug Quality?	184
2. OBJECTIVES AND ELEMENTS OF A COMPREHENSIVE QUALITY ASSURANCE PROGRAM	186
3. PROCEDURES FOR ASSESSING DRUG QUALITY	188
4. ORGANIZING A QUALITY ASSURANCE PROGRAM	193
SUMMARY	195
REFERENCES	196
APPENDICES	
III.D.1. Bioavailability of Drug Products	197
III.D.2. Centers Performing Quality Control Tests	200
III.D.3. WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce	201
III.D.4. National Drug Control Agencies Participating in the WHO Certification Scheme	203

How Good are the Drugs: Quality Assurance

The purpose of quality assurance in public drug supply systems is to make certain that each drug reaching a patient is safe, effective, and acceptable. When "quality control" is mentioned, people often think of laboratory testing of drug samples. Although such tests are important, they are only one part of a comprehensive quality assurance program which includes both technical and managerial activities.

The quality of a final drug product is determined by the raw ingredients, equipment, and technical know-how that go into producing and packaging it, as in most manufacturing processes. But unlike a steel bolt or a tailored suit, a drug is a dynamic product whose color, consistency, weight, and even chemical identity can change between its manufacture and its ultimate consumption. Furthermore, these changes can occur anytime between the production of the drug and its use many months later and thousands of miles away. A drug which passes all laboratory tests upon entry into a tropical country may be useless within a few months if it has not been properly formulated and manufactured, if the packaging is not of the correct type or is of poor quality, or if storage and transportation conditions have been improper.

It is the dynamic nature of drugs which requires that an effective quality assurance program include both the technical activities involved in performing or reviewing quality control laboratory tests and the managerial activities involved in supplier selection, preparation of contract terms, monitoring supplier performance, and establishing and enforcing drug inspection procedures at points throughout the distribution network.

Even though quality assurance is discussed here with procurement activities, it is obvious that quality assurance spans the entire supply process from selection to patient use. It is as relevant for programs which purchase all of their supplies or have their supplies donated as it is for programs which produce their own pharmaceuticals. Quality assurance includes not only the activities which guarantee that the drugs in the central medical stores are of high quality, but also the activities required to assure that this quality is maintained to the point of consumption by the patient.

Assessment Guide III.D. poses questions intended to help health officials, technical consultants, and other individuals involved in drug supply to reflect upon current quality assurance activities within their own programs.

1. DRUG QUALITY

To establish and maintain an effective quality assurance program it is necessary to have an understanding of the meaning of drug quality, the determinants of the quality of the drugs which reach the patient, and the reasons why health officials should worry about drug quality.

ASSESSMENT GUIDE III.D.
Quality Assurance Activities

- Are there stated policies and practices aimed at assuring drug quality? If so, what are these policies and procedures? Are they being followed?
- Who is responsible for the quality of drug purchases and donations? What type of training do these individuals have?
- What methods are used to assess and maintain the quality of drugs purchased by or donated to the program?
- Has drug quality ever been an issue in your program? In what way? What effect has this had on public health? On the program? On medical practitioners?
- Is a 100 percent physical inspection made of all drugs received? Are the inspectors (checkers) well-trained and adequately supervised?
- Are laboratory analyses ever used to assess drug quality? Who performs these analyses? Is the testing laboratory reliable? Is there a government quality control laboratory which can be used for such testing?
- If the government repackages drugs into course-of-therapy packets or other smaller packages, is there a control system for assuring that adequate enclosure is maintained?
- What are the conditions during transportation of drugs? Can the drugs be seriously affected by these conditions? What improvements in transportation conditions are possible?
- Are storage conditions periodically evaluated at the ports of entry? At the central warehouse? At district and regional stores? In hospital pharmacies? At health centers and rural health posts? If so, who is responsible for these evaluations and what type of training do the responsible individuals have?
- Is there any system for village health workers, general practitioners, and other health personnel at peripheral facilities to report problems with drug quality?

. What is "Drug Quality"?

Pharmaceutical scientists have many ways of defining and testing drug quality. Established quality standards are published periodically in the form of pharmacopoeias which provide detailed descriptions of drug characteristics and analytic techniques. Commonly accepted pharmacopoeias include, among others, the International Pharmacopoeia published by the World Health Organization, the United States Pharmacopoeia (U.S.P.), the British Pharmacopoeia (B.P.), the European Pharmacopoeia, the French Pharmacopoeia, the Nordic Pharmacopoeia, the Pharmacopoeia of Japan, the Swiss Pharmacopoeia, the Canadian Formulary, and the West German Pharmacopoeia.

For the purposes of primary health care, the most important characteristics of a drug product to consider are its identity, purity, potency, uniformity, and bioavailability.

Identity -- The correct active ingredient should be present in the product. This characteristic is generally the easiest to guarantee, although occasionally a supplier will have such poor quality control that the wrong active ingredient is present and not detected. In most cases where analysis reveals a different ingredient present, there is a packaging or labeling error.

Purity -- Most drugs are made with a variety of ingredients which are added for bulk, consistency, color, etc. The important point is that drugs not contain potentially harmful contaminants, significant quantities of other drugs (sometimes found when manufacturing plants are not kept clean), or bacteria and other micro-organisms which could infect the patient.

Potency -- The drug should have enough of the active ingredient. Most pharmacopoeias specify a content range, such as 95 to 110 percent of the amount written on the label, rather than an exact amount. Thus a 100 milligram tablet of hydrochlorothiazide must have between 95 and 110 milligrams of hydrochlorothiazide in it when it is manufactured, and this amount must still be present when the original package is opened at any point before the expiration date. To assure a long shelf-life, reliable manufacturers often produce drugs with the maximum allowable amount (e.g., 110 milligrams, rather than 95 milligrams). This provides a margin of safety for slight losses in potency.

Uniformity -- The consistency, color, shape, and size of tablets, capsules, creams, and liquids should not vary from one dose to the next. Problems in uniformity often do not influence the safety or effectiveness of a drug, but they generally do influence the acceptability of a drug to pharmacists, medical practitioners, and patients. Futhermore, lack of uniformity may suggest problems in identity, purity, or potency.

Bioavailability -- Occasionally a drug will appear normal and pass all analytic tests, but when given to the patient it will not be properly absorbed into the blood stream and will not, therefore, have its intended therapeutic effect. Bioavailability is the rate and extent of absorption of a drug from a specific dosage form. In practice, most drug preparations are sufficiently bioequivalent for routine medical practice; that is, the bioavailability of most drugs -- whether bought by their medical (generic) name or by a brand name -- is adequate enough to assure that the patient receives the intended effect from the drug. Furthermore, standard pharmacopoeias are beginning to

incorporate testing standards which will assure bioavailability. Nevertheless, bioavailability is an important factor in the selection of certain drugs and it is therefore discussed in greater detail in Appendix III.D.1.

Although there are other technical pharmaceutical science terms which could be introduced here, the concepts of identity, purity, potency, uniformity, and bioavailability provide a definition which is practical and complete for evaluating drug quality in clinical medicine.

b. What Determines Drug Quality?

The quality of a drug coming off the production line is determined by the raw ingredients, the plant environment, the manufacturing equipment, and the technical know-how invested in developing the drug and the manufacturing process. But the drug reaching the patient may be quite different. The packaging, transportation conditions, storage conditions, and many other factors influence the quality of the drug at the end-use level. These factors are summarized in Figure III.D.1.

The influences can be cumulative. This is especially true of factors involved in the manufacturing process. For example, differences in the selection of particular inactive ingredients which are used to give tablets their bulk and consistency may have no effect on the color, texture, or chemical quality of a drug until the immediate container is opened in a hot, humid environment. Then, depending on the manufacturer's choice of ingredients, the tablet may remain firm and dry, or it may become moist and crumble within a matter of days. The humidity of the factory during packaging may also have an important effect. If glucose-electrolyte sachets are not packaged under very low humidity, moisture enters the sachet and may result in chemical changes in the glucose which makes it difficult to use. Similarly, the amount of grinding, the thoroughness of mixing, the choice of packaging, the maintenanc of packaging equipment, and the other factors shown in Figure III.D.1. can have an effect which may be immediately evident or may not appear until the drug reaches the point of consumption.

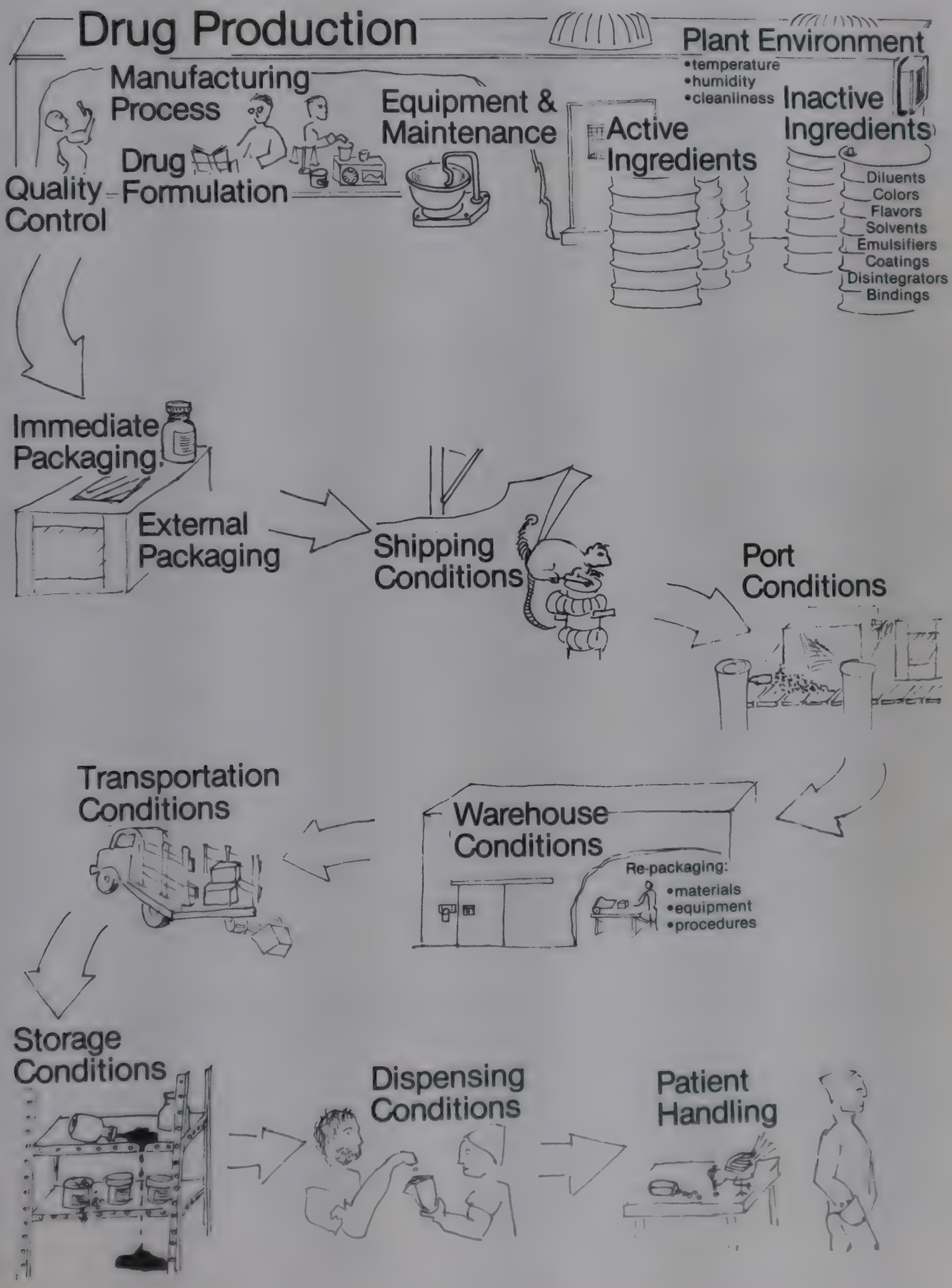
It is because of the dynamic nature of drug products and the cumulative effects of the production process, packaging, storage conditions, and other factors that quality assurance must occur at all levels in the supply system.

c. Why Worry About Drug Quality?

Doctors prefer to prescribe high quality drugs, pharmacy personnel prefer to dispense high quality drugs, and patients prefer to consume high quality drugs. But in reality, what difference can it make if a drug does not meet established quality standards, reaches its expiration date, or seems to have been spoiled by the local environment? Many thoughtful physicians and pharmacists in developing countries will knowingly use drugs which have exceeded their shelf-lives or whose surface has become slightly discolored. Usually there are no serious consequences, but there is the potential for adverse effects, the most important of which should be kept in mind when considering issues of drug quality. These include:

Figure III. D. 1.

Determinants of Drug Quality



Loss of Potency -- Reduced drug potency or drug strength can occur when the bioavailability is poor, when it reaches its expiration date, when a supplier fraudulently or unknowingly dilutes a drug, or when improper storage conditions are used. Most drugs have a margin of safety so that even after the expiration date they contain close to 100 percent of the stated active ingredient. With many drugs -- for example, cold remedies and minor pain killers -- reduction of up to 50 percent in the content of the active ingredient will have no serious consequence. But for other drugs -- for example, antibiotics, heart pills, seizure medications, and asthma medications -- the exact content is important; for these drugs careful supplier selection, maintenance of proper storage conditions, and attention to expiration dates are critical.

Medication errors -- The most serious errors occur when the wrong active ingredient has been used or when the mixing process has resulted in too high or too low a concentration of the drug. Such errors are uncommon with established manufacturers.

Toxic degradation -- A prevalent fear is that when drugs expire or change appearance in tropical climates they degrade into toxic products. In fact, tetracycline is virtually the only common drug with which this occurs. A much more frequent problem is contamination.

Contamination -- Contamination of drug products with micro-organisms -- usually bacteria or fungi -- occurs occasionally and the consequences can be quite severe, particularly in the case of injectable drugs. For this reason, experienced public procurement officials are often much more selective about supply sources for injectable items. Contamination of creams, syrups, and other drugs in jars and tubes is especially common in tropical environments, but the consequences are quite variable, depending on the type of organism and drug involved. Usually such contamination has little harmful effect. However, if the drug is to be used in the eye or in other delicate areas, contamination may have catastrophic effects. Suppliers of such products should be carefully selected. Finally, drugs are occasionally contaminated during their manufactur by particles from other drugs. In small quantities this is unimportant, unless the contaminant is highly allergenic (e.g., penicillin). Adherence to good manufacturing practices should eliminate such contaminants.

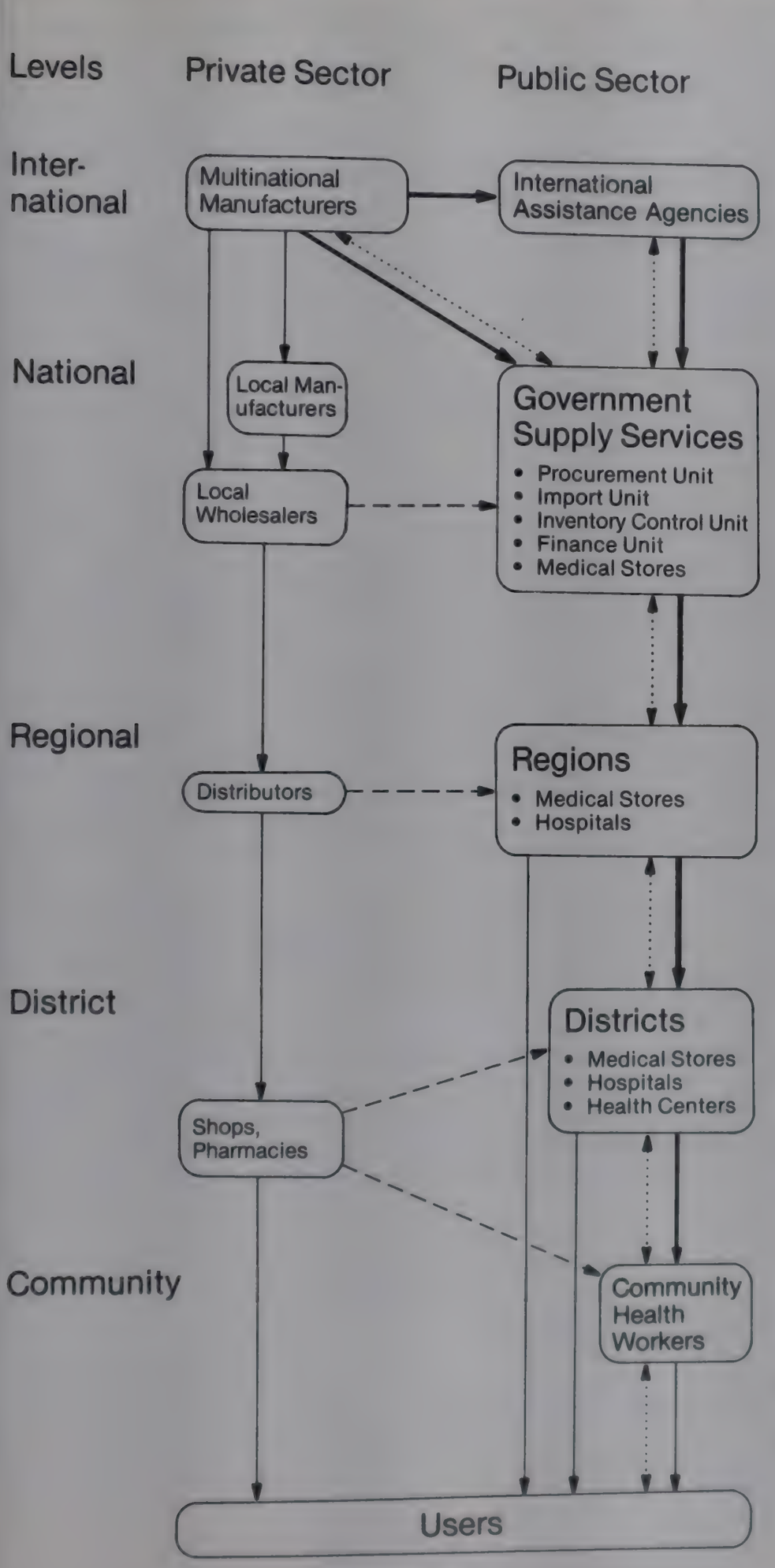
Although other minor problems may arise from poor drug quality, these four potential hazards are the most significant.

2. OBJECTIVES AND ELEMENTS OF A COMPREHENSIVE QUALITY ASSURANCE PROGRAM

If drugs remained unchanged from the time of manufacture to the time of consumption, then the only objective of a quality assurance program would be to assess the quality of drugs manufactured, purchased, or donated. However, drugs are dynamic products; a quality assurance program that is comprehensive must address a variety of other issues as well. The important elements of a quality assurance program are as follows:

Figure III.D.2.

Elements of a Comprehensive Quality Assurance Program



SUPPLIER SELECTION

- Gather accurate information about reliability of new suppliers.
- Maintain supplier file on past performance.
- Request and test samples from selected prospective suppliers.

PORT CLEARANCE

- Monitor storage conditions to assure that proper temperature, light, cleanliness, and humidity are maintained.
- Ensure that required Certificates of Quality are presented with import documents.

SHIPMENT ACCEPTANCE

- Inspect shipment contents to assure adherance to contract specifications.
- Test samples, either routinely or for suspect products.

REPACKAGING

- Participate in selection of repackaging systems to assure that they are suitable to the local environment.
- Monitor packaging equipment, materials, and techniques to assure that adequate enclosure is maintained.

STORAGE

- Monitor conditions to assure that acceptable storage environments are maintained.

TRANSPORTATION

- Review transportation modes, routes, and schedules to prevent serious lapses in cold chain or other storage requirements.

DISPENSING

- Assure adequacy of storage conditions at dispensing points.
- Review selections of bottles, envelopes, papers, and other dispensing materials.
- Maintain a system to verify quality of drugs at the final dispensing points.

(1) Assure, to the greatest extent feasible, that suppliers are selected whose formulation and packaging are such that, under the storage and transportation conditions which are reasonably attainable in the country, the drugs maintain an acceptable level of quality. A well-written supply contract should help to achieve this objective.

(2) Determine that the composition of drugs which are accepted from commercial suppliers and donor agencies meets specified quality standards at the time of delivery.

(3) Confirm that the packagings (immediate containers, external packaging, crates, etc.) meet contract requirements and are sufficient to withstand handling and storage within the country.

(4) Oversee repackaging activities and dispensing practices as necessary to confirm that drug quality is maintained until consumption by the patient.

(5) Monitor storage and transportation conditions to be sure that drugs are properly protected from the environment.

These five objectives should be included in a comprehensive plan and considered carefully by senior officials in any drug supply program. Their implementation must occur throughout the procurement and distribution process.

The main points at which drug quality can be positively or negatively influenced by the drug supply system are shown in Figure III.D.2. Quality assurance is clearly a widely shared responsibility and, therefore, it should not be assigned entirely to one individual pharmacist or one unit of the program. If effective and safe drugs are to reach patients, all of the quality assurance activities noted in Figure III.D.2. must occur.

At many points in the system, limited resources make optimal monitoring and maintenance of drug quality difficult, if not impossible. Inevitably there must be compromises between preferred and attainable standards. But it is essential that these compromises be made knowingly and by the appropriate individuals. It is of no value for the procurement unit to spend large sums of money on sample testing of drugs if storage conditions and re-packaging techniques result in the complete degradation of the drugs before they reach the patient. Likewise, it is unreasonable to invest in a costly modern drug warehouse if the individuals responsible for supplier selection choose inexpensive but unreliable suppliers and, as a result, acquire drugs which lack potency.

3. PROCEDURES FOR ASSESSING DRUG QUALITY

Many of the activities included in Figure III.D.2. are covered in other chapters and will not be discussed in detail here. In this chapter, we describe some of the most commonly used techniques for assessing the quality of drug purchases and donations.

Figure III.D.3. categorizes and describes quality control procedures currently in use by public procurement programs in various parts of the world. In general, these are procedures designed to ensure that drugs received by the program meet acceptable standards of quality. They do not include procedures relevant to maintaining the quality of drugs as they move through the distribution network.

Unfortunately, quality assessment procedures are often costly and there is no "best system" which provides the greatest quality assurance at the lowest price in all countries. The World Health Organization has advocated a system of economical, less technically demanding Basic Tests for commonly used drugs. As these tests are developed, the process of quality assurance should be greatly facilitated. (WHO, 1981)

When choosing specific procedures and establishing a quality assurance system, public officials and their advisors must balance the costs of quality control procedures and possibly higher drug prices (in cases where these procedures result in the loss of low-price suppliers), against the gains that result from these quality assurance procedures. These gains can be evaluated in terms of reduced expenditures for medical complications resulting from poor drug quality, as well as in terms of the health benefits of having safe, effective drugs.

Country Study III.D.1. describes the activities followed in several countries, and shows in particular how careful supplier selection can be used to assure quality. This is one of the least expensive methods for quality assurance and probably the one most frequently used by professional procurement officials in Western countries. Large-scale buyers such as major hospitals and government armed forces rely on prudent supplier selection and often make limited use of laboratory analyses or individual batch certification.

There are several means by which to evaluate the reliability of potential suppliers (see Chapter III.C. for a fuller discussion). One important measure is a producer's adherence to good manufacturing practices (GMP). The World Health Organization has established GMP for pharmaceutical products and these standards parallel those enforced by the U.S. Government Food and Drug Administration (FDA) and similar national drug control agencies in other countries. The requirements include criteria for personnel, facilities, equipment, materials, manufacturing operations, labeling, packaging, quality control, and, in most cases, stability testing. (Requirements for stability testing vary from country to country; nevertheless, assurance that adequate stability testing is performed is necessary for public drug supply programs in developing countries.) Formulations and packagings must be shown to maintain drug stability under normal test conditions if drugs are to survive under the conditions often found in developing countries.

Where national drug control agencies exist (see Appendix III.D.4.), adherence to GMP is enforced by a system of inspections and other regulatory controls. Recent reports of GMP inspections and drug recall histories can be obtained by writing national drug control agencies. Often a supplier must approve or at least expedite requests for performance reports from national drug control agencies; a supplier's failure to obtain such reports for the buyer makes its past performance suspect. GMP reports can sometimes be obtained from other procurement programs or from international agencies such as the Crown Agents in Great Britain. (See Appendix III.F.1. in Chapter III.F. for address.)

Figure III.D.3.

Procedures to Assess the Quality of Drugs Supplied to Public Procurement Programs

TYPE OF PROCEDURE	DESCRIPTION OF PROCEDURE	COMMENTS
A. Restricted Supplier Selection		
1. Internationally known firms only.	Tender boards and purchasing officers exclude from consideration any supplier which they do not feel has an international reputation for reliability. Limits the supplier pool to primarily developed countries. Assumes that such firms have more rigorous quality control procedures and more capable laboratories and equipment.	Procedure itself entails no expense, but often results in higher drug acquisition costs. This is not always the case, since the internationally known firms sometimes submit the lowest bids. Depends largely on reputation. Subjectivity of procedure allows for "influence" selections.
2. Certificate of Origin and Certificate of Free Sale required.	Purchaser is informed of which country the drug was manufactured in and is assured that the manufacturer is authorized to sell in that country. Then relies on the country of manufacture to enforce quality control standards.	Dependable technique only if the buyer knows the quality standards of the country of origin. Assumes supplier honestly uses the same quality control for export drugs.
3. Lowest priced suppliers omitted.	Purchaser excludes from consideration suppliers offering the lowest prices. In doing so purchasers will routinely accept offers that are 10 to 30% higher than the lowest and occasionally those that are more than twice as high. Assumes that the cheapest suppliers are sacrificing quality for price.	A procedure which itself entails no expense, but which raises acquisition costs. Assumption that low bidder has sacrificed quality for price does not always hold.
B. Inspection for Good Manufacturing Practices (GMP)		
4. GMP report by manufacturer's drug regulatory authority required.	As suggested in the WHO Certification Scheme on the Quality of Pharmaceuticals Moving in International Commerce, all suppliers are required to present a certificate from their national drug regulatory authority stating that the plant is routinely inspected and that the manufacturer complies with GMP. New inspections generally occur only every 2 to 3 years.	Major "cost" of this approach is time delay required to receive reports. Most useful as part of registration procedure for restricted tenders. Depends upon inspection standards of the country of origin, which vary. Commonly used technique among institutional buyers in developed countries.
5. GMP report from reliable procurement program or national drug regulatory agency outside country of manufacture.	Where national drug regulatory agency standards are not sufficient to assure that the manufacturer complies with all GMP requirements, reliable manufacturers may be inspected by agencies from other countries or by major procurement programs (e.g., United Nations groups or large hospital groups). Manufacturers supply a list of past inspections and request a copy of the report from an inspector of the buyer's choice.	Provides a more independent evaluation than that provided by the supplier's own drug control agency. Delay involved in obtaining such reports likely to be greater than for those obtained from the country of origin.
6. Purchaser performs GMP inspection.	The Purchaser sends a qualified individual from his own staff to inspect the manufacturer's plants. More reliable if the inspector is a pharmacist or qualified technician who has received formal training in GMP inspections through WHO, UNIDO, or a national drug regulatory agency.	Potentially costly procedure when initial training and ongoing travel expenses are considered. Provides a reliable assessment of suppliers in countries where national drug control agencies are inadequate or non-existent. Inspectors sometimes prone to "influence" by their host supplier whom they are inspecting.
C. Physical Inspection of Each Shipment		
7. Inspection by independent agent in export-	Through an established procedure, an independent agent such as a member of the Société Générale de Surveillance inspects the packing and samples each shipment prior to export to check	Adds slightly to the cost of drugs. Usually very reliable, although occasionally such agents are in error.

	who has included this cost in his price.	
8. Inspection by purchaser's own wharf and/or warehouse inspectors.	Each shipment inspected in its entirety by staff trained in taking samples and in judging the physical appearance of products. All shipments compared with the purchase order and invoice or packing slip. Good checking routines serve quality control function as well as insurance functions.	A routine part of professional procurement practice. Inspections also uncover supplier negligence, fraud, and deviations from contract specifications. Adequate training and ongoing supervision of inspectors crucial.
D. Laboratory Analysis		
9. Manufacturer's quality control batch testing report.	As part of GMP, each batch should have a record which contains an analytical report showing that the individual batch complies with the specifications for the drug. Copies of these reports are required to be submitted with each batch received.	Usually no additional charge, but reliability quite variable. Probably should be trusted only where national drug control agency is known to enforce GMP.
10. Independent laboratory batch analysis report.	Sample testing of each batch is performed by a private quality control laboratory which is independent of the manufacturer, such as the Société Générale de Surveillance. The analysis can be billed to the supplier, who includes this cost in his price.	Allows buyer to consider equally suppliers at all price levels. Good reliability, provided the buyer has selected the laboratory and the testing is based on a random sample drawn the laboratory.
11. Testing by manufacturer's national drug regulatory agency.	Sample testing of each batch is performed by the national drug regulatory agency in the exporting country. This function is an optional part of participation in the WHO Certification Scheme.	As reliable as the national control agency, provided sampling is random. May entail a fee for the agency.
12. Pre-purchase sampling by purchaser.	Suppliers are required to submit samples with their offers. Samples beginning with the lowest-priced supplier are tested until one or more are found which conform to specifications. Samples from suppliers whose quality is known from previous testing are often assumed to be of the same quality and not tested.	Costly if the buyer does not have a QC laboratory of his own. Time-consuming. Subject to deceit, since the supplier provides a sample of his selection.
13. Pre-acceptance sampling by purchaser.	Samples from each batch received at the central warehouse are sent for testing. Payment is not authorized until favorable results are received.	As for Procedure No. 12, except that the number of samples tested is greatly reduced.
14. Testing by exception	Samples are sent for testing by purchaser only when a pharmacist, physician, or other health professional raises a question about drug quality.	A useful procedure, since the number of tests is usually small, high-risk samples are chosen, and elimination or vindication of suspect suppliers is important.
15. Post-acceptance testing.	After drugs are purchased and shipments accepted for payment, testing of samples is done on a systematic basis. Generally not every batch is tested, but a schedule is established which assures that each product will be tested at least once during a supply contract. When testing shows a significantly substandard drug, the drug is recalled.	Used where public quality control laboratories exist, but capacity is limited and tests must be scheduled.
16. Local stability testing.	For all products or for a selected group of products, samples are requested from potential suppliers and sent to the local warehouse or storeroom which experiences the greatest climatic extremes. The samples are kept under those conditions for six to twelve months or more before physical inspection and, often, laboratory analysis.	Useful when the buyer is considering new sources of supply for high-volume or costly items, is very concerned about drug stability, and is willing to wait for six to twelve months to make a final decision.

Country Study III.D.1.

Quality Assurance in Selected Countries

Papua New Guinea -- The majority of the products currently purchased by the Pharmaceutical Services Section (PSS) are from known suppliers whose products have previously been tested and with whom the PSS has had good results. For new suppliers or new items from an older supplier, samples are requested and sent to the national drug control laboratory in Canberra, Australia, for a fee of about U.S.$40. Usually the sample from the lowest bidder is tested first. Samples are also drawn randomly from goods received, since suppliers occasionally send goods of different quality than the original samples.

For critical items, items in new packaging, or items about which stability is in question, several samples from the first shipment will be put aside in one of the hotter, more humid stores and checked periodically for deterioration. In 3 to 12 months a sample may be sent to the Canberra laboratory. PNG's experience is that, except for a small number of products which require cold room storage (e.g., insulin, vaccines, some antibiotics), the majority of pharmaceutical products will withstand the climate without air conditioning, provided the packaging has been adequately tested. (1978)

Malaysia -- For packaging materials and raw materials purchased for the government production unit, samples are routinely tested in the analytical laboratory. For finished dose products, the tendency is to keep to well-known and reputable suppliers and to do little actual sample testing. The tender period allows time for the staff to request samples of products from new suppliers or old suppliers bidding on a new product. In general, a new supplier is not used unless his products have been tested. (1978)

Costa Rica -- The Social Security Fund (CCSS) funded a well-equipped air-conditioned laboratory which opened in the mid-1970's and is capable of performing chemical analysis for most drugs, biological analyses for antibiotics and vaccines, and pyrogen testing for injectables. In 1978 the laboratory was staffed and equipped to perform 400 tests per month, but had been pushed by the volume demand to 600 per month. The value of the laboratory is demonstrated by the results of the 1976-1977 testing: 79 of the 320 samples submitted from the bid were rejected (32.78%). Even after this screening, 292 of the 1661 samples collected at the time of delivery were rejected (17.57%). Since that time, the percentage of rejections has declined, possibly reflecting the effectiveness of pre-purchase testing.

Because of difficulties with suppliers, the CCSS instituted a requirement that QC results be completed before payment is made. It takes 1 to 4 weeks for the lab to turnaround a sample. For tests of samples from a bid and samples taken from warehouse receipts, the CCSS pays for the first test performed, but charges the supplier for any additional tests that are required. (1978)

Sri Lanka -- Soon after the formation of the State Pharmaceuticals Corporation (SPC) to manage drug importation, the public and medical profession began to question the quality of some drugs. Hence, the SPC makes considerable efforts to assure quality. It requires that a supplier (1) register with SPC, (2) provide a Certificate of Origin with each shipment, and (3) bear the expense of testing by an independent laboratory chosen by the SPC. In addition, the SPC occasionally sponsors local studies of bioavailability. Because suppliers' own certificates of quality were often found to be unreliable, and a well-known international quality control agency was not consistently reliable, the SPC developed a list of independent QC labs which they recommend to suppliers to perform the QC checks.

Although a merit rating system was devised, it has not been implemented. The Tender Board which decides on suppliers relies on its own memory of experience with the company, the reports of Board members who have inspected suppliers' facilities, and, to some extent, information from a Registration System. The Registration System is being used to ascertain (1) bank references, (2) trade references (large hospitals, government agencies, etc., in other countries to whom they may write for information on reliability and quality), and (3) names of government agencies under whom they fall (from which a confidential GMP and performance report may be requested). (1978)

Peru -- The Basic Medicine Program attempts to assure the potency and pharmacological integrity of its medicines through several mechanisms. First, contracts are awarded preferentially to known companies, generally those with an international reputation, though sometimes to locally owned companies. Second, laboratory testing is done by exception: for any product which pharmacists, doctors, or nurses observe to be physically abnormal in any way or for which the clinical results suggest lack of potency. Third, there is a procedure for systematic post-acceptance sampling of all routine drug purchases. During the first five years of the program, Peru had limited test facilities and careful selection of suppliers was the primary means of attempting to assure quality. The creation in 1976 of a national control laboratory led to the policy of testing all items on the Official Requisition.

If a product fails because the content of the active ingredient is above or below the allowed levels, the company is fined and is not considered in future bids on that product. If quality is poor due to contaminants, the wrong active ingredient, etc., the contract is cancelled and the drug is recalled. (1978)

Alternatively, some buyers with highly trained pharmaceutical staff perform their own inspections of potential suppliers.

Unfortunately, GMP reports are only as reliable as the agency performing them. While national drug control agencies in the major supplying countries are generally conscientious in their assessments, agencies in some countries have been found by public drug programs to be less reliable.

In addition to providing recent GMP reports and drug recall histories, many national drug control agencies have agreed to participate in the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce (see Appendix III.D.3.). The names and addresses of these agencies along with notes on any special conditions set by individual agencies appear in Appendix III.D.4. Many of the participating agencies will provide individual batch certificates or certify the accuracy of the manufacturer's analyses. Laboratory analyses of samples from individual batches can also be obtained through international quality control organizations such as Société Générale de Surveillance (General Superintendence) or other agencies listed in Appendix III.D.2.

Independent laboratory analysis of individual batch samples provides a dependable, but costly and often time-consuming, addition to a quality assurance program. The expense of such testing can be reduced if the services of a government pharmaceutical control laboratory are available to the supply program. Construction of a laboratory where one does not already exist should be considered with the same cautious thoroughness and the same type of feasibility study used to consider pharmaceutical production facilities (Chapter III.F.). If analyses are performed by foreign laboratories, then foreign exchange and billing problems may be reduced by requiring the suppliers to pay the laboratory themselves. Such an arrangement should be clearly described in the purchase contract.

Many buyers keep drug analysis costs to a minimum by "testing by exception." In this case, drugs are analyzed only when a supplier or a specific drug is suspect.

Regardless of other quality assurance procedures in use, physical inspection of each drug shipment should be performed. This includes not only verification of adherence to contract specifications and a count to be sure the order is complete, but also a visual inspection of samples of all items to spot any gross abnormalties. The training of competent checkers can be an economical and rewarding means of assuring drug quality as well as reducing losses due to supplier negligence or fraud.

4. ORGANIZING A QUALITY ASSURANCE PROGRAM

The most important step in creating a comprehensive quality assurance program is the establishment of administrative procedures for quality assurance activities, which include training and supervision of the staff members involved.

Central to the operation of most well-run drug procurement systems is a qualified pharmacist with some training or experience in industrial pharmacy and in procurement. Such an individual can be invaluable in establishing and overseeing quality control practices best suited to local requirements. He or a qualified assistant should participate in drug selection, in setting technical specifications for drug contracts, in reviewing supply offers and selecting suppliers, and in reviewing storage and transportation facilities. He should also coordinate any drug testing and help to train the inspectors who check drug shipments (see Chapter IV.D.).

In some government programs qualified pharmacists are employed at all levels, including the district hospitals, and they are expected to oversee local storage and transportation conditions. In addition, they report problems or questions concerning individual drugs to the main office. In other countries, locally-trained dispensers (Chapter V.B.) assist in much of the day-to-day work required for close monitoring of drug quality.

Development of expertise in the pharmaceutical sciences is valuable in any drug program large enough to have its own staff. Some fellowships are available to assist in the training of pharmacists and other pharmaceutical staff (see Chapter VI.D.).

In addition to pharmacists and pharmaceutical assistants, there are other staff members involved in quality assurance, and adequate training and supervision of these individuals should be an important focus of quality assurance efforts. Physicians, health administrators, and others involved in supplier selection should become sufficiently knowledgeable about the factors influencing drug quality to make informed decisions about supply sources. Port-clearing personnel should be trained to identify the categories of drugs requiring special storage and transportation conditions. Clerks responsible for inspecting drug shipments should receive formal training in inspection procedures. Inspectors must be familiar enough with drug labeling and with packaging materials to determine whether contract conditions have been met with regard to the correct drug, dosage, packaging, etc. When government repackaging is done, laborers should be aware of how their work might affect drug quality. Finally, physicians, nurses, medical auxiliaries, and other individuals responsible for handling drugs throughout the distribution network should receive some form of systematic education about the factors which influence drug quality and their individual responsibilities for assuring that the drugs dispensed to patients are safe and effective.

Another important component of an effective quality assurance program is the information system. Chapter III.C. on supplier selection mentioned the use of a Supplier File and a Product File. These are ledgers or card files which are used to record the experience with individual suppliers and with individual drug products. They should be used to record any instances of substandard quality of drugs or their packaging.

Ideally, forms and procedures should exist for pharmacy staff and health care providers at all levels of the system to report instances of suspected lapses in drug and/or packaging quality. A simple reporting form would suffice. Whenever possible the "evidence" should be returned to the central medical stores and full credit for the return should be given to the facility or health worker reporting the problem. This type of reporting system is particularly important, since many of the quality problems in primary care

programs are apparent only after a product has been rigorously tested by the local environment and suboptimal storage and transportation conditions.

Inevitably, as Figure III.D.2. illustrates, quality assurance is a widely shared responsibility. But it should not be a responsibility which falls between gaps in the organizational structure of the procurement program. Responsibilities for the review and preservation of drug quality at all levels in the supply system should be clearly established. If a drug becomes ineffective or unsafe by the time it reaches the patient, then all of the other activities of the system have been in vain.

SUMMARY

The purpose of quality assurance in public drug supply systems is to make certain that each drug reaching a patient is safe, effective, and acceptable. A comprehensive quality assurance program includes both technical and managerial activities, spanning the entire supply process from drug selection to patient use.

Established quality standards are published periodically in pharmacopoeias. For the purposes of primary health care the most important characteristics of a drug are:

- identity
- purity
- potency
- uniformity
- bioavailability.

Drug quality is affected by the manufacturing process, packaging, transportation and storage conditions, and other factors; and these influences may be cumulative.

If a drug does not meet established quality standards, reaches its expiration date, or seems to have been spoiled by the local environment, the possible consequences are:

- loss of potency
- medication errors
- toxic degradation
- contamination.

A comprehensive quality assurance program must consider:

- that suppliers are selected whose quality standards are acceptable
- that drugs received from commercial suppliers and donors meet specified quality standards at the time of delivery
- that packagings meet contract requirements, and can withstand handling and storage conditions
- that repackaging activities and dispensing practices maintain quality
- that storage and transportation conditions are adequate.

When establishing a quality assurance program, public officials must balance the costs of quality control procedures against the gains that will result from having safe, effective drugs.

Administrative procedures must be established for quality assurance activities. This includes training and supervision of staff members at all levels of the supply process, and an effective information system.

CHAPTER III.D. REFERENCES

American Pharmaceutical Association: The Bioavailability of Drug Products, 1978. Cumulative Edition. Washington, D.C.: American Pharmaceutical Association, 1978.

Cooper, M.S. (ed.): Quality Control in the Pharmaceutical Industry, Volumes 1, 2, and 3. New York: Academic Press, Inc., Vol. 1, 1972; Vol. 2, 1973; Vol. 3, 1979.

Deasy, P.B. and Timoney, R.F. (eds): The Quality Control of Medicines. New York: Elsevier Scientific Publishing Co., 1976.

Drug and Therapeutics Bulletin Editorial: Storage and Shelf-Life of Drugs: When is it important? Drug and Therapeutics Bulletin 15 (21): 81-83, 1977.

Feinberg, M.: How We Seek Quality in Competitive Drug Procurement. Pharmaceutical Times 39: 36-41, December, 1973.

Jeffrey, L.P. et al: Assuring the Quality of Medications Stored in Patient Care Areas. Washington, D.C.: American Journal of Hospital Pharmacists 32: 283-285, March, 1975.

UNIDO: Appropriate Industrial Technology for Drugs and Pharmaceuticals, Monographs on Appropriate Industrial Technology No. 10. New York: United Nations Industrial Development Organization, 1980.

U.S. Department of Defense: Quality Control Depot Serviceability Standards. Alexandria, VA: Defense Supply Agency, 1974.

WHO: Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. Geneva: World Health Organization, 1978.

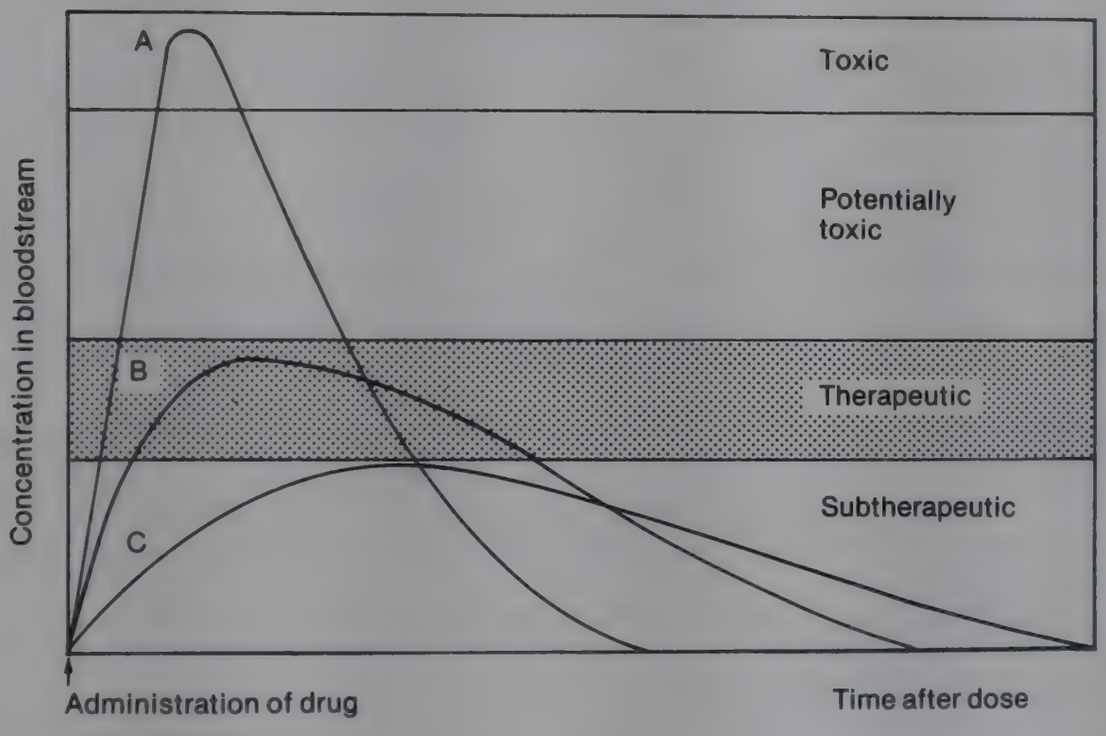
WHO: WHO Expert Committee on Specifications for Pharmaceutical Preparations, 27th Report. Technical Report Series, No. 645. Geneva: World Health Organization, 1980.

WHO: Basic Tests for Pharmaceutical Substances: Suggested Procedures. WHO/PHARM/81.506, English only. Geneva: World Health Organization, 1981.

Appendix III.D.1.

Bioavailability of Drug Products

Bioavailability is defined as the rate and extent of absorption of a drug from a specific dosage form. In other words, it is the speed and completeness with which a drug administered in a specific form (e.g., tablet, capsule, intramuscular injection, subcutaneous injection, etc.) enters the blood stream. Bioavailability is important in drug selection because there are preparations which, even though they contain the correct amount of active ingredient, do not give the expected therapeutic result; the active ingredient is released too quickly, too slowly, or incompletely. The following figure gives the bioavailability curves for three hypothetical oral preparations, all of which contain the same total dose of the same active medication:



(Adapted from UNIDO, 1980)

Preparation A releases the drug so quickly that it reaches toxic levels and then rapidly becomes subtherapeutic (ineffective). Preparation B provides a relatively steady, therapeutic level of medication in the blood stream. Preparation C releases the drug so slowly and incompletely that therapeutic levels are never reached. Obviously, preparation B represents the best bioavailability.

The rate and extent to which a drug is absorbed from a specific preparation depends upon the nature of the other ingredients in the preparation (solvents, binders, coloring agents, coatings, etc.); the formulation or way in which the ingredients are combined; the packaging; and several other factors. The best laboratory test for bioavailability is the dissolution test (not to be confused with the disintegration test). Unfortunately, the standard pharmacopoeias have only recently begun to include dissolution tests as part of their requirements. Generally, if a drug passes an established dissolution test, then its bioavailability is acceptable. If a drug does not pass dissolution testing, then more sophisticated tests are necessary to determine the bioavailability.

Since most drugs do not have a bioavailability problem and manufacturers cannot supply test results for all products, and since government procurement programs generally cannot do such testing, it is important to decide which drugs have a potential bioavailability problem. The following table provides some guidelines:

Potential for Bioavailability Problems		
HIGH	INTERMEDIATE	LOW
• slowly disintegrating compressed tablets	• suspensions	• solutions
• enteric (stomach) coated forms	• chewable tablets	
• time-release preparations	• capsules	
• narrow range between therapeutic and toxic doses	• rapidly disintegrating compressed tablets	

Adapted from American Pharmaceutical Association, 1978.

In addition to considering the likelihood of a bioavailability problem, procurement officials should consider the potential harm to the patient if there were a problem. For cold remedies, pain-killers, and other medications for symptomatic relief, there is little likelihood of harm being done by slow or incomplete absorption of a medication. But bioavailability may be quite important for heart medicines like digoxin and digitoxin (where toxicity is common and sometimes serious), insulin (where reliable absorption is important to prevent complications), anti-seizure drugs (where the blood level must be maintained within a certain therapeutic range), and anticoagulants (where variability of dosage may lead to serious hemorrhage). Fortunately, for simple antibiotic preparations, bioavailability is almost never a problem.

Thus, during procurement procedures for a public drug program, suppliers should be selected with care, and bioavailability considered for those products which have a high potential for bioavailability problems and for which a problem in bioavailability might harm the patient. This might mean requesting bioavailability studies from the supplier, requesting reports from national drug control agencies, such as the Food and Drug Administration in the U.S.A., having a government laboratory or medical school perform bioavailability tests (as in Country Study III.D.2.), or simply limiting the selection to a small number of well-known suppliers whose products have always been reliable.

Country Study III.D.2.

Bioavailability Testing by a National Drug Procurement Agency

Because of early experiences with products of questionable bioavailability, the State Pharmaceuticals Corporation (SPC) began sponsoring bioavailability testing. The testing was usually coordinated by members of the medical school department of pharmacology. The following is a report which appeared in the S.P.C. News:

Studies on Bioavailability of Imported Drugs: Nitrofurantoin

Three brands of Nitrofurantoin from Smith Kline and French (India), Polfa (Poland), and Unique (India), respectively, were compared in-vivo and in-vitro.

In-Vivo: 100 mg. (2 tablets) were administered to 10 health volunteers in a fasting state, according to a latin square design, and the urine levels of Nitrofurantoin were estimated by a colorimetric method after 1, 2, 4, and 6 hours. The total urine output was also measured.

Nitrofurantoin Excreted in 6 hours in mg.

	S.K.F.	Polfa	Unique
No. of estimations	10	10	10
Average excretion	48.2	44.9	39.9
Standard error	2.62	3.01	3.17

An analysis of variance gave F=2.03, confirming that there was no significant difference in the urinary excretion of the 3 brands of Nitrofurantoin 6 hours after oral ingestion of 100 mg.

In-Vitro: Dissolution studies were carried out on these 3 brands using the stirrer-flask method in (a) simulated gastric fluid and (b) simulated intestinal fluid. The average time for 50% dissolution in simulated gastric fluid is given below:

	S.K.F.	Polfa	Unique
T_{50} (time for 50% dissolution) in minutes	23	25	26.5

The differences in the values are not statistically significant. A correlation was found between the in-vivo results and the in-vitro results in simulated gastric fluid, the correlation coefficient being 0.95. It is therefore possible to use in-vitro testing to assess the bioavailability of Nitrofurantoin tablets.

Conclusion: In-vivo studies on the urine levels of Nitrofurantoin showed that there was no signficant difference between the 3 brands, SKF, Polfa, and Unique. In-vitro studies confirmed this result.

Reprinted from The Prescriber 5(1): 31-32, 1977. Published by the State Pharmaceuticals Corporation of Sri Lanka.

Appendix III.D.2.

Centers Performing Quality Control Tests

National Biological Standards
Laboratory
Department of Health
Box 462, City
21-23, London Circuit
Canberra, A.C.T. 2601
AUSTRALIA

Service de Controle des Medicaments
Association Pharmaceutique Belge
137 rue Stevin
1040 Brussels
BELGIUM

Drug Research Laboratories
Drugs Directorate
Health Protection Branch
Department of National Health
and Welfare
Tunney's Pasture
Ottawa, Ontario K1A OL2
CANADA

State Institute for the
Control of Drugs
Srobarova 48 - Vinohrady
100 41 Prague 10
CZECHOSLOVAKIA

Institute of Drug Research
and Control
Chelmska 30
00-725 Warsaw
POLAND

Office Intercantonal de Controle
des Medicaments
Erlachstrasse 8
3000 Berne 9
SWITZERLAND

Societe Generale de Surveillance S.A.
(General Superintendence)
Minerals and Chemicals Division
1, place des Alpes
Case postale 898
CH - 1211 Geneve 1
SWITZERLAND

Laboratory of the Governmental Chemist
Cornwall House
Stamford Street
London SE1 9NQ
England
UNITED KINGDOM

The Pharmaceutical Society of
Great Britain
Laboratory of the Department of
Pharmaceutical Sciences
1 Lambeth High Street
London SE1 7JN England
UNITED KINGDOM

Food and Drug Administration
Office of Pharmaceutical Research
and Testing
Bureau of Drugs
Department of Health, Education,
and Welfare
Public Health Service
Washington, D.C. 20204
UNITED STATES OF AMERICA

* This listing is provided to assist officials in locating reliable quality control laboratories which perform drug analysis at a reasonable price.

Included are agencies which have assisted in such activities in the past. However, this listing should not be considered inclusive nor should it be taken as an endorsement of the agencies listed.

Appendix III.D.3.

WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce

Part I-Certification of Pharmaceutical Products

1. For the purpose of this Certification Scheme "pharmaceutical product" means any medicine in its finished dosage form, intended for human use, that is subject to control by legislation in the exporting Member State and in the importing Member State.

2. A pharmaceutical product exported or imported under this Certification Scheme would be certified by the competent authority of the exporting Member State on a Certificate of Pharmaceutical Products, issued at the request of the interested party, to be sent to the competent authority of the importing Member State, which would decide to grant or to refuse the authorization for sale or distribution of the certified product, or to make the authorization conditional on the submission of supplementary data.

3. The issue of the Certificate of Pharmaceutical Products would be subject to the conditions required by the competent authority of the exporting Member State in order to certify that:

(a) the product is authorized for sale or distribution within the exporting Member State (if not, the reasons therefore would be stated on the certificate); and

(b) the manufacturing plant in which the product is produced is subject to inspections at suitable intervals to show that the manufacturer conforms to requirements for good practices in manufacture and quality control, as recommended by the World Health Organization, in respect of products to be sold or distributed within the country of origin or to be exported.

A suggested layout of a Certificate of Pharmaceutical Products with explanatory notes is attached.

4. If certificates of individual batches of products covered by a Certificate of Pharmaceutical Products are required, such certificates could be issued either by the manufacturer or by the competent authority of the exporting Member State, according to the nature of the product and the requirements of the exporting Member State or of the importing Member State. The batch certificate would indicate the name and dosage form of the product, the batch number, the expiry date and storage conditions, a reference to the Certificate of Pharmaceutical Products, and a statement that the batch conforms either to the requirements of the competent authority for sale or distribution within the exporting Member State (with reference to the authorization) or, as the case may be, to published specifications, or to established specifications to be provided by the manufacturer. The certificate could also include data on packaging, labelling, nature of the container, the date of manufacture, results of analysis, and other data.

Part II-Exchange of information

1. Upon the request of the competent authority of the Member State into which a pharmaceutical product covered by this Certification Scheme is to be or has been imported, the competent authority of the exporting Member State should provide:

(a) information on the implementation of the Requirements for Good Practices in the Manufacture and Quality Control of Drugs as recommended by the World Health Organization;[1]

(b) information on controls of the product as exercised by the competent authority of the exporting Member State;

(c) the names and functions of the persons designated to sign certificates of individual batches of the product to be exported.

Information on general and specific standards of quality control of the product to be exported, in so far as they are required to comply with legislative provisions of the importing Member State, could also be supplied with the consent of the manufacturer.

2. In the case of quality defects of products imported under this Certification Scheme that are considered to be of a serious nature by the importing country, not attributable to local conditions and circumstances, and appearing after the introduction of a particular batch into the importing Member State, the competent authority should notify the occurrence, together with the relevant facts, to the competent authority of the exporting Member State that had issued the Certificate for the product concerned, with a request to institute inquiries. Conversely, if the competent authority of the exporting Member State ascertains serious quality defects, that competent authority should notify the competent authority of the importing Member State.

Part III-Participating Member States

1. Each Member State agreeing to participate in the Certification Scheme shall communicate (a) the name and address of its principal authority to be considered as competent within the meaning of the Certification Scheme, and (b) any significant reservations relating to its participation, to the Director-General of the World Health Organization, who would notify all other Member States.

2. Exporting Member States participating in the Certification Scheme shall ensure that:

(a) authorization for sale or distribution of pharmaceutical products is subject to appropriate testing measures, by the competent authority, designed to ensure their quality, and that adequate laboratory facilities are available for this purpose.

(b) the pharmaceutical industry is obliged to conform to requirements for good practices in the manufacture and quality control of drugs as recommended by the World Health Organization;

(c) the competent authority is empowered to conduct appropriate investigations to ensure that manufacturers conform to the requirements referred to in (b), including, for example, the examination of records and the taking of samples;

(d) the inspectors of the services of its competent authority have appropriate qualifications and experience.

3. Exporting Member States participating in the Certification Scheme should, whenever possible, ensure that the international nonproprietary names, whenever available, are used in the description of the composition of the product on the Certificates and, as far as possible, appear on the labelling of pharmaceutical products to be exported under the Certification Scheme.

[1] It is realized that in some countries this may require the consent of the manufacturer

CERTIFICATE OF PHARMACEUTICAL PRODUCT(S) [1]

Name and dosage form of product: .....

Name and amount of each active ingredient: [2] .....

.....

.....

.....

.....

Manufacturer, and/or when applicable, the person responsible for placing the product on the market:

.....

.....

.....

Address(es): .....

It is certified that:

☐ This product has been authorized to be placed on the market for use in this country.

Number of permit and date of issue (if applicable): .....

.....

☐ This product has not been authorized to be placed on the market for use in this country for the following reasons:

.....

.....

.....

It is also certified that (a) the manufacturing plant in which the product is produced is subject to inspections at suitable intervals, and (b) the manufacturer conforms to requirements for good practices in the manufacture and quality control, as recommended by the World Health Organization, in respect of products to be sold or distributed within the country of origin or to be exported. (See Explanatory Notes.)

.....
(Place and date)

.....
(Signature of designated authority)

[1] This form may be adapted to cover several products of the same manufacturer.
[2] Use, whenever possible, international nonproprietary names (INN) or national nonproprietary names.

EXPLANATORY NOTES

Certificate of Pharmaceutical Product(s)

This certificate is intended to define the status of the pharmaceutical product and its manufacturer in the exporting country. It is issued by the competent authority in the exporting country in accordance with the requirements of the competent authority of the importing country. It may be required by the importing country at the time of the first importation and subsequently if confirmation or updating is required.

The requirements for good practices in the manufacture and quality control of drugs mentioned in the certificate refer to the text adopted by the Twenty-eighth World Health Assembly in its resolution WHA28.65 (see *Official Records* No. 226, Annex 12, Part. 1).

Batch certificates

If certificates of individual batches of products covered by a Certificate of Pharmaceutical Products are required, such certificates could be issued either by the manufacturer or by the competent authority of the exporting Member State, according to the nature of the product and the requirements of the exporting Member State or of the importing Member State. The batch certificate would indicate the name and dosage form of the product, the batch number, the expiry date and storage conditions, a reference to the Certificate of Pharmaceutical Products and a statement that the batch conforms either to the requirements of the competent authority for sale or distribution within the exporting Member State (with reference to the authorization) or, where appropriate, to published specifications, or to established specifications to be provided by the manufacturer. The certificate could also include data on packaging, labelling, nature of the container, the date of manufacture, results of analysis, and other data.

Appendix III.D.4.

National Drug Control Agencies Participating in the WHO Certification Scheme

Notes:

1 Agency states that it does not assume the responsibility for giving individual batch certificates.

2 Agency states that it does not assume the responsibility for giving individual batch certificates except for certain antibiotic drugs.

3 Agency states that quality certificates will be issued by the manufacturers themselves.

4 Agency states that it will not give individual batch certificates for products that are manufactured for export only.

5 Agency states that the registration procedure is not obligatory with regard to products manufactured for export only.

6 Agency states that some information can be supplied only with the consent of the manufacturer or sponsor company.

Direcção Nacional de Medicamentos
e Equipamentos
C.P. 50
Luanda, ANGOLA

Dirección Nacional de Medicamentos
y Alimentos
Defensa 120 - 5º piso - Of. 5055
1345 Buenos Aires, ARGENTINA

Australian Department of Health [1,6]
P.O. Box 100
Woden, A.C.T. 2606, AUSTRALIA

Bundesministerium für Gesundheit [1,5]
und Umweltschutz
(Federal Ministry of Health and
Environmental Protection)
Stubenring 1
A-1010 Vienna, AUSTRIA

Department of Pharmacy Affairs
and Drug Control
Directorate General of Curative
Medicine
P.O. Box 42
Manama, BAHRAIN

Service de l'Inspection générale de
la Pharmacie
Ministère de la Santé publique et
de la Famille
Cité administrative de l'Etat
Quartier Vésale
1010 Bruxelles, BELGIUM

Departamento de Farmacologia y
Laboratorios
Ministerio de Previsión Social y
Salud Pública
La Paz, BOLIVIA

Director-General
Department of Health
Ministry of Health
36 Theinbyu Street
Rangoon, BURMA

Ministerio de Salud
Departamento Apoyo a los Programas
Santiago, CHILE

Directeur des Pharmacies
Ministère de la Santé publique
et des Affaires sociales
Brazzaville, CONGO

Departamento de Drogas Estupefacientes,
Controles y Registros de Medicamentos
Ministerio de Salud
San José, COSTA RICA

The Drugs Council
c/o Ministry of Health
Nicosia, CYPRUS

The National Health Service [1]
St. Kongensgade I
DK-1264 Copenhagen K, DENMARK

---

* This listing is a compilation of the lists published in the WHO Chronicle Vol. 31, No. 12 (1977); Vol. 33, No. 7/8 (1979); and Vol. 34, No. 11 (1980); of countries which have agreed to participate in the "Certification Scheme on the Quality of Pharmaceutical Products moving in International Commerce", as recommended to Member States by the Twenty-eighth World Health Assembly, in its resolution WHA 28.65.

General Administration of Pharmacy
Ministry of Public Health
Cairo, EGYPT

Ministerio de Salud Pública y
Asistencia Social
Calle Arce No. 827
San Salvador, EL SALVADOR

Pharmacy Division
Ministry of Health
P.O. Box 1234
Addis Ababa, ETHIOPIA

The National Board of Health [1]
Lääkintöhallitus
Siltasaarenkatu 18A
SF-00530 Helsinki 53, FINLAND

Service central de la Pharmacie
et des Médicaments
Ministère de la Santé
14, avenue Duquesne
75007 Paris, FRANCE

Director of Pharmaceutical Services
Pharmacy Division
Ministry of Health
P.O. Box M-44
Accra, GHANA

Ministerio de Salud Pública y
Asistencia Social
Palacio Nacional
Guatemala City, GUATEMALA

The Government Analyst/Commissioner
of Food and Drugs [1,6]
Analyst/Food & Drug Department
Ministry of Health
19-21 Evans & Lyng Streets
Georgetown, GUYANA

Ministry of Health and Social Security
Pharmaceutical Division
Reykjavik, ICELAND

INDIA
For certificates of pharmaceutical
products, write individual states:

Drugs Controller & Food (Health)
Authority [1]
Z.P. 1-168
Tarnaka
Secunderabad 500017
Andhra Pradesh, INDIA

Director of Health Services [1]
Delhi Administration
15 Sham Nath Marg
Delhi 54
Delhi, INDIA

Director
Drugs Controller Administration [1]
Gujarat State
Multi-Storeyed Building, 2nd Floor
Lal Darwaja
Ahmedabad I
Gujarat, INDIA

Drugs Controller, Kerala [1]
Public Health Laboratory
P.O. Red Cross Road
Trivandrum I
Kerala, INDIA

Drugs Controller, Karnataka [1]
Palace Road
P.B. No. 5377
Bangalore 560001
Karnataka, INDIA

Commissioner of Food & Drugs Administration [1]
Maharashtra State
Griha Nirman Bhawan
Opp. Kala Nagar
Bandra (East)
Bombay 51
Maharashtra, INDIA

Director of Public Health & Preventive
Medicine [1]
79-81, Anna Salai
Madras 6
Tamil Nadu, INDIA

Food & Drugs Controller [1]
Directorate of Medical & Health Services
Lucknow
Uttar Pradesh, INDIA

Director of Drugs Control, West Bengal [1]
College Square (West)
Calcutta 73
West Bengal, INDIA

Food and Drug Organization
Ministry of Health and Welfare
Building No. 4
Old Shemiran Road
Teheran, IRAN

Pharmaceutical Division
Ministry of Health
8 a, Hurkania Street
Jerusalem, ISRAEL

Ministère de la Santé
Direction générale des Services
pharmaceutiques
00100 Rome, ITALY

Pharmaceutical Affairs Bureau [1]
Ministry of Health and Welfare
1-2-2, Kasumigaseki, Chiyoda-ku
Tokyo 100, JAPAN

Pharmacy and Supplies Department
Ministry of Health
P.O. Box 86
Amman, JORDAN

The Chief Pharmacist, R.L.
Division of Pharmacy
Ministry of Health & Social Welfare
Monrovia, LIBERIA

Direction de la Santé publique
B.P. 177
Nouakchott, MAURITANIA

The Permanent Secretary
(Attention: Chief Government Pharmacist)
Ministry of Health
Edith Cavell Street
Port Louis, MAURITIUS

Ministério da Saúde
Secretariado para a Cooperação
Internacional
Serviço Farmaceutico
C.P. 264
Maputo, MOZAMBIQUE

Division of Clinical Services
Department of Health
P.O. Box 5013
Wellington, NEW ZEALAND

Federal Ministry of Health
Food and Drugs Administration and
Laboratory Services Directorate
P.M.B. 12525
Federal Secretariat
Ikoyi
Lagos, NIGERIA

The Health Services of Norway
Pharmaceutical Division [3]
P.B. 8128, Oslo-Dep
Oslo 1, NORWAY

The Director-General of Health [1]
Ministry of Health, Social Welfare
and Population Planning
Government of Pakistan
Islamabad, PAKISTAN

Director
Departamento de Farmacia y Drogas
Ministerio de Salud
Apartado 2048
Panama, PANAMA

Département de la Technique médicale
et de la Pharmacie
Ministère de la Santé et de
l'Action sociale
15, Miodowa Str.
00-923 Warsaw, POLAND

Direcção-Geral de Saúde
Serviços de Farmácia et Medicamentos
Alameda D. Afonso Henriques 45
Lisbon 1, PORTUGAL

Bureau of Pharmaceutical Affairs
Ministry of Health and Social Affairs
The Unified Government Building
Seoul, REPUBLIC OF KOREA

Ministère de la Santé
Direction pharmaceutique et de
l'Equipement médical
Ilfov 6
Bucarest, ROMANIA

Ministère de la Santé publique
Direction générale des Pharmacies
B.P. 640
Kigali, RWANDA

Direcção da Farmácia
Ministério da Saúde
São Tomé, SAO TOME AND PRINCIPE

Ministère de la Santé publique et de
l'Action sociale
Inspection des Pharmacies
153, rue Blanchot
Dakar, SENEGAL

Subdirección General de Farmacia [3]
Dirección General de Sanidad
Plaza de España 17
Madrid, SPAIN

Director of Medical Services
Department of Pharmacy
Ministry of Health
P.O. Box 5
Mbabane, SWAZILAND

National Board of Health and Welfare
Department of Drugs [3]
Box 607
751 25 Uppsala, SWEDEN

Director of Pharmaceutical Affairs
International Health Affairs Directorate
Ministry of Health
Damascus, SYRIAN ARAB REPUBLIC

Secretary-General of Food and Drug
Administration
Ministry of Public Health
Devavesm Palace
Bangkok II, THAILAND

Direction de la Pharmacie, des
Laboratoires et des Médicaments
de la Santé
Place Bab Saadoun
Tunis, TUNISIA

General Directorate of Pharmacy and
Pharmaceutical Products [3]
Ministry of Health and Social Assistance
Ankara, TURKEY

Department of Pharmacies and Supplies
Ministry of Health
P.O. Box 848
Abu Dhabi, UNITED ARAB EMIRATES

Department of Health and Social Security
Medicines Division [1,4]
Finsbury Square House
33-37A, Finsbury Square
London EC2A 1PP
UNITED KINGDOM OF GREAT BRITAIN
AND NORTHERN IRELAND

Ministry of Health
P.O. Box 9083
Dar Es Salaam
UNITED REPUBLIC OF TANZANIA

Food and Drug Administration [2]
Public Health Service
Department of Health, Education,
and Welfare
Washington, D.C. 20201
UNITED STATES OF AMERICA

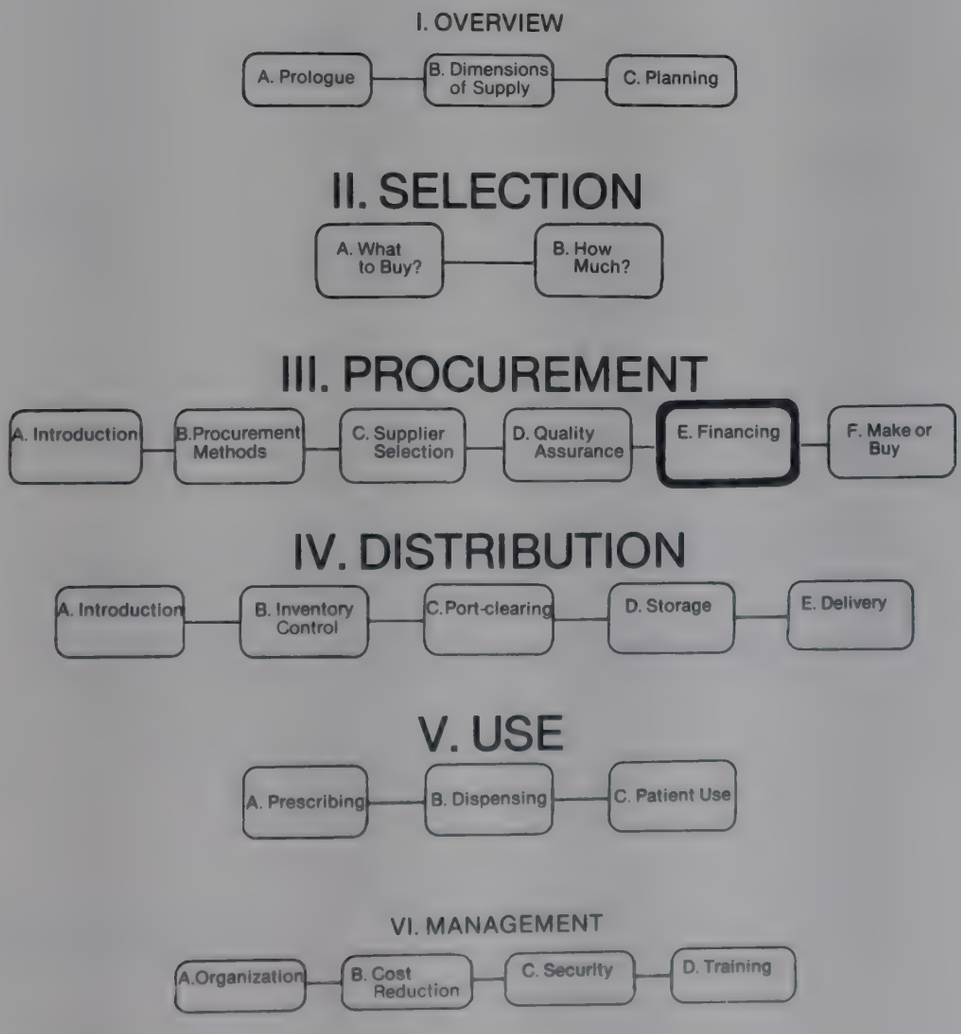
Federal Committee for Labour, Health
and Social Welfare
Bulevar Avnoja, 104 SIV-II
11070 Belgrade, YUGOSLAVIA

Direction des Services pharmaceutiques
Département de la Santé publique
B.P. II.998
Kinshasa I, ZAIRE

The Permanent Secretary and Director
of Medical Services
Ministry of Health
P.O. Box 205
Lusaka, ZAMBIA

Chapter III.E.

Who Will Pay: Financing Drug Supplies



	Page
1. THE COSTS OF DRUG SUPPLY	209
a. Drug Costs	211
b. Operating Costs	212
c. Development Costs	213
2. DETERMINING GOVERNMENT FINANCING NEEDS	213
3. FUNDING ALTERNATIVES	215
a. Evaluation Criteria	218
b. Assessing the Alternatives	220
External Funding	220
Non-Governmental Agencies	221
National Budget	221
Regional/Provincial/State Budget	222
Community Contribution	223
Insurance	223
Individual Consumer Expenditure	224
c. Choosing a Funding Strategy	226
4. DRUG SALES PROGRAMS	226
a. Drug Pricing	228
b. Revolving Drug Funds and the Pipeline Concept	230
SUMMARY	239
REFERENCES	240

Who Will Pay: Financing Drug Supplies

Expenditures on pharmaceuticals vary widely from country to country. In countries such as the United States, France, Italy, and Japan, annual expenditures on drugs may exceed an average of U.S.$35.00 per person. In contrast, some of the poorest countries consume an average of less than U.S.$0.50 per year in pharmaceutical products. Where government health programs serve a large, defined section of the population, annual expenditures of roughly U.S.$1.00 per person have been found by some governments to provide adequate coverage of the population. Unfortunately, there is no standard by which a government or district can determine whether it is spending the "right" amount on drug supply. While a program serving 1,000,000 people and spending only U.S.$500,000 per year on pharmaceuticals is quite likely underserving its population, another program of the same size but spending U.S.$5,000,000 may be barely supplying basic needs if all drugs are bought by brand name at retail price and drug waste is extensive.

Just as the total amount spent varies greatly, the sources of funding and the willingness of the public to pay out-of-pocket for medicines varies. Public health planners are sometimes surprised at how much even the poorest individuals will pay for overpriced or marginally useful medicines sold at local pharmacies and shops. A survey in one rural area in central Asia revealed that individuals spend over seven percent of their disposable income on health needs, and 37% of that for drug purchases. In a Latin American country just embarking on a rural health program, community health workers turn to private pharmacies to replenish their stocks when program supplies fail them; this is necessary, they say, to maintain interest in health services.

Of the many aspects of public drug supply covered in this manual, financing represents the most vexing challange and, frequently, the most frustating limitation for public health officials. Present or projected demand nearly always exceeds anticipated resources, making efficient use of available funds imperative. Careful drug selection, wise procurement practices, systematic waste reduction, and other measures described throughout the manual are essential for making the best use of limited funds. Whatever the resources available for drug supply, it is important to understand the categories of expense involved, and to fully evaluate potential sources of financing for drug supply. Therefore, this chapter will first consider the costs of drug supply and then proceed to evaluate some of the funding alternatives. Assessment Guide III.E. provides an introduction to some of the questions which will be considered.

. THE COSTS OF DRUG SUPPLY

The expense of supplying pharmaceuticals constitutes a large proportion of the total cost of most health care systems. Consequently, it is important that these costs be accurately estimated. Under-budgeting for the drug supply system can have drastic implications for the cost-effective delivery of basic health care. In Afghanistan, for example, the Parwan-Kapisa Pilot Project

ASSESSMENT GUIDE III.E.
Financing Public Drug Supply

- How much money, approximately, is spent each year for drugs supplied by the government? For drugs bought by the public for commercial pharmacies, from physicians, and elsewhere? What is included in these estimates? The wholesale cost of drugs only? The cost plus distribution costs?

- Where do the funds come from for drugs supplied through government health programs? From import taxes, property taxes, and other general revenue? From insurance funds? From charitable organizations? From fees paid by patients? From local community funds?

- If drugs are supplied through government programs, what is the cost of supplying the drugs? How much is paid to suppliers for the drugs? What are the annual expenditures for storage? In-country transportation? Pre-Packaging? Waste? Salaries and wages for procurement staff, distribution staff, and other personnel?

- What are the effects of the current drug funding mechanisms on the availability of drugs? The use of drugs? The cost of drugs? The extent of drug distribution to rural or poor populations? And the extent to which drugs are properly used?

- If government programs establish drug prices, what criteria are used to establish these prices? The wholesale cost of each drug? The ability of patients to pay? The type of drug? Are preventive pharmaceuticals such as vaccines provided free of charge and symptomatic treatments like cold medicines sold for a fee?

- How do drug prices affect the use of health services? How do they influence the willingness on the part of patients to use drugs?

- For new programs, are the development costs for the program separated from the operating costs? Are operating costs anticipated in advance? Or are current grants for development being used to create programs for which insufficient operating funds will be available?

demonstrated that improved drug supply, in combination with improved supervision and training, dramatically affected health service delivery. (In this project, operating costs were kept nearly constant, but by substituting a limited range of inexpensive generic drugs for a long list of expensive and frequently inappropriate drugs, the number of complete courses of therapy that could be provided was increased several hundred percent. Patient demand quickly expanded to meet supply. As a result, daily attendance more than tripled and the estimated unit cost per patient served decreased from approximately U.S.$0.80 to $0.25.)

The costs of drug supply can logically be broken down into three categories:

- drug costs,
- operating costs of the system that procures, stores, and distributes the drugs, and
- development costs of that system.

These three categories are not independent. For example, the costs of drugs influence the quantities consumed, and thus have implications for both the development and operating budgets of the drug supply system. Similarly development expenditures made one year frequently have important implications for future operating budgets. Often, small "savings" in operating expenditures have hidden costs related to excessive inventory holding costs and inefficient use of infrastructure, e.g., warehouses, that greatly exceed the original savings.

Division of costs should also be made according to whether foreign exchange will be required. In many countries (e.g., Guinea-Bissau, Tanzania, Burma) foreign exchange is tightly controlled and is inadequate to fund the many justified uses. It is particularly important in these countries to carefully analyze the foreign exchange implications of development expenditures.

Finally, only after costs have been accurately estimated is it possible to realistically establish budgetary needs and, for a drug sales program whose objective is to recover those costs, to set public drug prices.

a. Drug Costs

All payments made to get drugs into the Ministry of Health's supply system are included in this category. The Ministry's supply system is con-

Figure III.E.1.

Principal Components of Drug Cost

Component	Foreign Exchange* Required
1. Manufacturer's price	Yes
2. Freight	Yes
3. Insurance	Yes
4. Demurrage	Frequently
5. Customs	
6. Port Charges	
7. Quality Assurance	Variable

*Assumes majority of drugs are imported, which currently holds true in most countries.

sidered as starting when a Ministry official signs to acknowledge receipt of the drugs. Ministry expenses, e.g., personnel and communications services, are not included. Some of the principal components of drug cost are included in Figure III.E.1. which indicates also whether they are likely to require foreign exchange.

b. Operating Costs

The operating costs, or recurring costs, include those items that are routinely included in the Ministry of Health's annual budget. To estimate the operating costs of the drug supply system, each step in the process of selecting, procuring, and delivering drugs to the patient should first be identified. Then, the expenditure required to perform each step should be estimated by budgetary categories. Finally, to help assure that the money is available where it is needed, the Ministry department responsible for implementing the step and making the expenditure should be identified. For example, the drug supply system may rely on a centralized motor pool to provide

Figure III.E.2.

Example of Operating Budget Line Items

Budget Line Items	Foreign Exchange Required*	Dept. No.1	Dept. No.2
Personal Services			
Civilian Base Pay			
Additional Pay, Allowances			
Other Cash Remuneration			
Other Services			
Communications			
Printing, Printed Advertizing	Variable		
Utility Services			
Rental of Land and Buildings			
Maintenance and Repair			
Travel and Subsistance	Yes		
Freight and Handling	Yes		
Others (dues, taxes, etc.)	Variable		
Materials Supplies and Parts (MSP)			
General Supplies (inc. fuels)	Yes		
Transportation MSP	Yes		
Agricultural MSP	Yes		
Construction MSP	Yes		
Office MSP	Yes		
Scientific and Technical MSP	Yes		
Communications MSP	Yes		

* Assumes limited local capacity in many supply areas. This will vary from country to country.

ransport for drugs. The required fuel must be included in the motor pool's udget.

Figure III.E.2. gives a summary of the budget categories or line items sed in the operating budgets of one Ministry of Health. It also identifies he items likely to involve foreign exchange expenditure. It includes, by way f illustration, two columns in which the line item amounts can be broken down nto departmental allocations.

c. Development Costs

Development expenditures are made for items which are expected to have a working life of more than 1 year. They may also be called capital costs or start-up costs, since the bulk of these expenditures occur when the system is being started or significantly expanded.

It is often relatively easy for a country to obtain foreign aid to finance development costs. The items involved, especially buildings and vehicles, are visible, easily quantified, and relatively easy to put in place. These same items may not be so easy to maintain and operate. Care should be taken to estimate the operating budget and recurring foreign exchange requirements of any development expenditure. Donors are usually very reluctant to fund, on a continuing basis, the recurring costs associated with their development assistance. Development history is littered with examples of foreign-assisted projects which could not be maintained because recurring costs or foreign exchange requirements were more than the host country could afford.

Figure III.E.3. lists the major categories of development expenditure. It also shows the implications for annual operating costs, expressed as a percentage of the development expenditure.

2. DETERMINING GOVERNMENT FINANCING NEEDS

It is apparent from the preceeding discussion of drug supply costs that providing pharmaceuticals through public health services may be a costly endeavor. A public distribution system plagued by administrative inefficiencies, high drug losses, and erratic deliveries may in the long run prove more costly for a district hospital than would local purchases from a private wholesaler.

A key question to be answered is: What portion of future supply will be distributed in the public sector? Within the public sector, the strategy must specify what channels will be used: Health centers? Government-operated pharmacies? Village-level depots? In addition, the strategy may call for government procurement of all pharmaceuticals through a central agency, with a portion resold to the private sector. This would allow greater control of foreign exchange utilization, and possibly economies of scale in purchasing. Also, profit from sales to the private sector could subsidize in part the public sector program. Within the public sector itself, the choice of supply channels will have a strong effect on the costs of program operation and the options available for financing.

Figure III.E.3.

Development Cost Categories

Category	Annual Operating Cost Implication: Local Currency Equivalent as a Percent of Development Costs	Annual Operating Cost Implication: Foreign Exchange
1. Building Construction	5%	Small
2. Transportation Equipment	20%	Large
3. Furniture	5%	Nil
4. Office Equipment	10%	Small
5. Other Equipment, e.g., Packaging	20%	Significant
6. Personnel Training	(a)	Small
7. Technical Assistance(b)	-	-
8. Drug Pipeline (Inventory)(c)	-	Large

(a) Personnel Training is frequently used as an incentive in developing countries, but if trained personnel are to be retained in the position for which they were trained, the financial incentives associated with the position may have to be increased.

(b) Technical assistance may be necessary during the design and startup phase of a drug supply system. The presence or absence of technical assistance in this phase does not necessarily have long-run implications for operating costs.

(c) Filling the drug pipeline can be considered a development cost if the system has a built-in mechanism for financing the resupply of drugs that are distributed to consumers, e.g., a drug sales program. Pipeline capitalization is discussed in section 4 of this chapter.

Obviously, an integral part of financial planning is program planning. The planning process described in Chapter I.C. should serve as the basis for determining government financing needs and the requisite funding sources.

The results of the planning process must be quite specific, especially with regard to financial requirements. Though most countries have stated long-range goals, few have prepared operational plans in any detail beyond a five-year horizon. In fact, most long-range goals are so ambitious that policy-makers are quite reluctant to analyse their financial implications. Therefore, a financial analysis may have to begin with a limited technical analysis, which will take general goals such as "access of all to basic health services by year 19__", and translate these into quantitative estimates of the population to be served, the services to be provided, and the supply needs.

art or all of this work may have been done by planners of other program omponents, such as Health Manpower. Nevertheless, it is essential that the upply implications be explicitly considered if adequate financial planning is o occur.

3. FUNDING ALTERNATIVES

In many countries, the financing pattern for pharmaceuticals has evolved ver time and is frequently not the result of analysis and planning. Both ublic and private drug expenditures are underestimated, and analysis may lead o surprising findings. For example, in 1979, North Yemen spent more on

Figure III.E.4.

Options for Financing Public Drug Supplies

1. External (Foreign) Funding
   - Grant
   - Loan

2. Internal (Domestic) Non-Government Agencies
   - Charitable Facilities, etc.

3. National Budget
   - Specifically Identified Drug Supply Costs
   - Costs Included in Overall Health Budget
   - Costs Included in Other Ministry Budgets

4. Regional/Provincial/State Budgets
   - Specifically Identified Drug Supply Costs
   - Other Financial Support (e.g., Transportation, Supervision, etc.)

5. Community Contribution
   - Monetary Value of Donated Services

6. Insurance
   - Government-Paid
   - Employee-Paid
   - Individual-Paid
   - Mixture of Above

7. Individual Consumer Expenditure
   - Retail Pharmacies, etc.
   - In Health Facilities

8. Combinations of Above

importing drugs alone than was allocated for the entire national health budget. Few countries know how much the public and private sectors combined spend on drugs, or where the money comes from.

Current financing patterns are generally a result of many factors, including:

- Tradition
- Expectations of the population
- Form of government
- Availability of health resources
- Administrative capability of the government bureaucracy.

All of these factors must be taken into account when health care services are being improved or expanded and funding for the drug program, in particular, is being increased. Initially, the objective is to consider as many reasonable financing alternatives as possible. The complete listing of financing alternatives will vary somewhat from country to country, but the major options which are generally available are set forth in Figure III.E.4. In the analysis for a particular country, there may be additional sources of financing to be considered, and these should be added to the list. As far as possible, none of the sources should be eliminated from consideration until the assessment is completed. A creative approach to identifying potential funding sources -- including proposals such as the one illustrated in Country Study III.E.1. -- may prove highly productive.

Data Gathering

An important step will be to shed as much light as possible on the amount of money flowing from each of the sources currently being used. This should include:

- Current expenditure levels by each funding source
- Current drug sources, including a breakdown of government and private purchases
- Trend in recent years
- Projection of future availability for each.

In some cases, this data will not be available. However, experience has shown that when a serious effort is made to provide the best possible estimates, the information can be extremely useful in understanding what is possible in the future. Many policy-makers have an impression of current drug supply financing which is quite different from the facts which result from a careful study. This is particularly true of consumer expenditures, especially among the urban and rural poor, where a simple survey can often result in a major change in our understanding of who is now paying for drug supplies.

Keeping an Open Mind

Very often, in a particular country, one or more possible financing sources have traditionally been avoided as a matter of policy (e.g., "There shall be no charge for any supplies provided at a government health facility").

Country Study III.E.1.

The Health Stamp: A Proposal for Financing Drug Supply

A Health Stamp: For Better Use of Government Supplied Drugs and Interest in Health Services by the People

The Ministry of Health at the present time is providing drugs to health centers, hospitals, and other health institutions free of charge. This policy to provide basic drugs free of charge is admirable but may not be feasible forever. The cost of drugs is increasing substantially every year. Each year more health centers, hospitals, and health institutions are being opened all across the country to provide greater access to health care. Each year the population grows larger and the volume of free drugs distributed increases. The burden of providing ever increasing amounts of drugs falls heavily on the government. If the funds are not increased as the health system expands, then the level of assistance decreases proportionately.

Most countries throughout the world have found that in order to meet the increasing demand they have had to continually raise taxes. Other countries have found it more equitable to subsidize health services but charge a nominal fee for basic drugs provided. It has been shown, in fact, that patients take more interest in the services provided when they pay for drugs. A recent project in Parwan/Kapisa Province has demonstrated that people can afford to pay a nominal fee. Over six hundred families were interviewed and indicated that they paid on the average of U.S.$25.00 per family per year for medicine. Parwan/Kapisa Province may not be a typical province, but at least gives an indication of the annual expense families pay for health care.

This proposal suggests the government create a health stamp similar to a postage stamp. A nominal charge for all drug prescriptions would be fixed by the government -- perhaps U.S.$0.12. This "Health Stamp" would be available in post offices and regional finance offices throughout the country. Thus the collection and accounting of funds would be taken care of in an already established office of the government. No funds would be collected at the health center or hospital pharmacy, which would eliminate the chance of the possible misuse of funds. The stamps collected at the health institutions for each prescription would be pasted into the official register next to the prescription as proof of payment.

No.	Patient's Name	Father's Name	Village	Prescription	

Individuals might carry one or two stamps along with their identity cards so they would not have to go to the post office or finance office every time they needed drugs. There could be variations to the idea, for example, not collecting the minimum fee for preventive vaccinations such as small pox or tuberculosis, or no fee for children up to a certain age.

Careful consideration should be given to analyzing where the funds will come from in the future to pay for the ever increasing demand of drugs at health centers and other health institutions. (1975).

From: "A Proposal for the Creation of an Income-Producing Health Stamp", Management Sciences for Health, Ministry of Health, Kabul, Afghanistan, May 1975.

Other sources will not have been used for other reasons. It is particularly important to avoid eliminating such sources from further consideration. In many cases, careful evaluation of each possible source helps planners to see more clearly the costs and benefits of each, and this may lead to greater interest in considering sources not currently being used.

a. Evaluation Criteria

It is important to look systematically at all financing options to get a complete view and to be able to compare them. The various options will generally have both positive and negative features. The most significant factors to weigh include:

(1) Equity
(2) Efficiency
(3) Stability
(4) Flexibility
(5) Impact
(6) Feasibility

In a specific country or program, there may be other factors which can be identified, and which should be taken into account. We will now clarify what we mean by each of the criteria:

(1) Equity -- This is basically a subjective judgment, which takes into account the goals and beliefs of a specific society about what is "fair" or "just". One society may believe that it is most fair or equitable that individuals or households which require goods or services (such as medicines) should pay their full cost. Another may believe that it is most equitable for cost to be shared such that all individuals or households pay an equal price. Yet another may hold that cost should be assessed on the basis of ability to pay. Of course, there may be one standard applied to certain expenses (luxury cars, for example) and a different standard applied to health care in general, and medicines in particular. Obviously, different societies will arrive at different assessments of the equity of various financing options.

(2) Efficiency -- This refers to the relationship between the amount of resources put in from a given source and the amount of drug supply that results. For example, a foreign loan might include a stipulation that drugs must be bought from limited and, therefore, possibly very expensive suppliers, or shipped via specific -- often costly -- transport. The result is a relative low volume of drugs available for the money being put in. Some financing mechanisms may be so cumbersome that much of the money is spent for administrat

(3) Stability -- This is the extent to which resources are available in planned quantities without interruption. Funding from national health budgets may be very stable, or may fluctuate widely as policies or government revenues change. External donor funding is seldom stable over long periods.

(4) Flexibility -- Certain financing sources may reduce or improve the ability of drug supply to reflect local needs. For example, medicines supplied by non-governmental agencies may not change quickly in response to new public health priorities. Government budgets may require decisions far in advance

Figure III.E.5.

Comparison of Financing Options

	EQUITY	EFFICIENCY	STABILITY	FLEXIBILITY	IMPACT	FEASIBILITY
External Funding	++	++	--	+/-	+	?
Internal NGAs	++	++	+	+/-	0	+
National Budget	0	-	+	+/-	-	0
Regional Budgets	0	-	+	+/-	-	0
Community Contribution	+	+	+	+	+	++
Insurance	+	-	+	+	-	0
Individual Expenditure	-	++	++	++	-	++

0 Neutral Effect
\+ Favorable Effect
\- Unfavorable Effect
+/- Favorable and Unfavorable Effects

allocating drug money among programs or geographic areas, and these allocations may be impossible to change if they prove to be inappropriate later on.

(5) Impact -- The source of financing will usually have a decided impact on what drugs are supplied and who consumes them. An important case is the utilization of vaccines and other preventive medicines, which usually declines sharply if consumers must pay their cost rather than receive them without charge through public programs. Generally, "free" (no charge) drug supply will lead to higher utilization among the poor, within the limits of available supply. Drug availability and consumption may actually be higher under an appropriate sales program if costs are held low enough, and if the self-supporting nature of the program results in a sharp increase in the quantity that can be supplied.

(6) Feasibility -- This refers simply to whether or not it is possible to use a given financing source. Note that "feasibility" has been listed last among the factors. Clearly, this is the most important factor in practical terms: no matter how desirable a financing source may be with respect to the other criteria, unless it is "feasible", it must be rejected. We consider

feasibility last simply to do everything possible to avoid rejecting an option which has much to be said for it. By focusing attention on the positive aspects of a financing source, we may be encouraged to look much more carefully at the possiblility of using a source which in the past was considered "infeasible".

b. Assessing the Alternatives

In a specific country or program, each financing alternative should be carefully analysed using the criteria developed earlier. We must emphasize that the results will vary from one country to the next, depending on local culture, policies, resource constraints, and a host of other factors.

At the same time, certain general observations can be made about the various financing options. These will be useful in amplifying some of the points made earlier, and in providing an example of the kind of specific analyses which should be done for any given country. The analysis is presented in tabular form in Figure III.E.5.

(1) External Funding

Funding from external (foreign) sources such as international assistance agencies and bilateral aid programs is one source of funding, particularly for program development.

Equity -- Grant from richer country usually seen as equitable by donor and by recipient. Usually a loan at concessionary terms, with "grant" and true loan components. The loan component involves major inequity of obliging future generation to pay for consumption by present generation, unless some compensating investment is being made.

Efficiency -- Grant or concessionary loan very efficient in obtaining supplies at low cost for recipient country.

Stability -- Generally very poor, with commitments from donors rarely going beyond three to five years, with major uncertainty thereafter.

Flexibility -- Variable, depending on donor and specific agreement. Often very significant restrictions on types of drugs available, sources of supply, means of transport, etc. Also frequently accompanied by other related restrictions or demands.

Impact -- In a well-planned program, drugs can be carefully chosen by mutual agreement with view toward maximum impact on national health priorities.

Feasibility -- Varies. Can sometimes be increased by good planning and active solicitation of support from key donors such as UNICEF, AID, etc.

(2) Non-Governmental Agencies (NGAs)

Resources are often provided by private charities and other non-governmental agencies, usually reflecting voluntary contributions by one population segment to another. May be subsidized by foreign sources or by the national government.

Equity -- Voluntary contributions highly equitable. If NGA subsidized by foreign sources, then equity comparable to that of "External Funding". If national government subsidizes the NGA, then equity comparable to "National Budget".

Efficiency -- Typically highly efficient, due to modest salary levels, strong motivation, little bureaucracy. (Exceptions exist.)

Stability -- Usually good, since NGAs have own long-term objectives and reasonably constant resource base.

Flexibility -- Usually quite responsive to local needs, since orientation is to provide service. May respond slowly (or not at all) to changing national government priorities. May have institutional policies excluding or emphasizing specific activities/supplies (e.g., Family Planning).

Impact -- Promotes increased demand for specific services and supplies provided, since cost borne by NGA.

Feasibility -- Depends mainly on factors outside government control, but opportunities may exist to support, promote, and encourage increased activity by private non-governmental agencies.

(3) National Budget (Health, Other Department)

Drug supplies (or other goods and services) are often provided by "the Government" through its public programs. The drugs may appear to be free to the people, although they are financed by government revenues.

Equity -- Varies, depending on who, actually, is paying the cost of government-delivered drugs. In the developed countries, at least in principle, free government services to the poor are subsidized primarily by the more affluent, through progressive tax sources such as graduated income taxation. In the developing world, however, the largest source of tax revenue is typically taxation on foreign trade (except in the special cases where oil revenue or other non-tax support is available). This tends to be regressive, with the burden falling most heavily on the poor themselves. So, from the equity perspective, national budget financing should not be assumed to be much more "fair" than direct consumer charges.

Efficiency -- While there is great variation among countries, most do not merit high ranking for efficiency. The bureaucracy involved in revenue collection, government coordination, central administration, and service delivery usually does not compare favorably with the private sector. As a result, the amount of drug supply available, relative to the total cost involved, is not high.

Obviously, this is mainly a question of service delivery rather than financing, but services funded by the national budget are almost always delivered by the government itself. Even where national budget resources are given out as subsidies to other organizations, the cost of tax collection and general administration is large; and much of the tax-payers' contribution, in fact, goes toward supporting the bureaucracy rather than putting medicines in people's hands.

Stability -- Very good, in most cases. Except for major political or environmental changes, governments are able to set financial allocations based on long-term plans and current operations requirements.

Flexibility -- Generally good. Obviously can respond quickly to changing government priorities, and in principle can also adjust to shifts in population needs. Some bureaucratic constraints, such as the difficulty of changing budget levels within a year, or reallocating funds from one Department or geographic area to another.

Impact -- Again, since the consumer does not pay the cost (at the time of service, at any rate), government financing tends to shift consumption towards the drugs being supplied, and sharply increase demand.

Feasibility -- In general, national budget financing for drug supply is feasible only up to a certain level, and this level will typically be far below the financial requirements implied by long-range health goals. It is this factor which will usually require either that goals are lowered, or that additional sources of financing are needed.

(4) Regional/Provincial/State Budget

Equity -- Basically the same as for "National Budget", unless different sources of funds are used.

Efficiency -- Again, most comments about "National Budget" financing apply here. While the bureaucracy at lower levels may be less, some central-level economies of scale may be lost, and the overall cost of obtaining resources at this level will usually not be very different from the cost of central-level financing.

Stability -- Quite good. Again, see "National Budget". Can be expected to be slightly less stable than the national budget, which averages the risks of all parts of the country.

Flexibility -- Better, since local regions can respond more appropriately to their own needs. On the other hand, central policy-makers generally lose some control.

Impact -- See "National Budget".

Feasibility -- See "National Budget".

(5) Community Contribution

Resources for drug supply may be provided by the community or external resources supplanted by direct contributions from the community.

Equity -- Varies, depending on whether the cost within the community is spread evenly or shouldered by those able to pay, reducing the risk to individuals and/or subsidizing supplies and services to those unable to pay.

Efficiency -- Generally very good, due to avoiding large bureaucracy. Community funds can usually be collected at low cost and applied directly to needed activities.

Stability -- Potentially very good, since community itself decides whether or not it wants to continue. May be a problem at early stages if lack of initial success or demonstrated results causes funding to dry up.

Flexibility -- A major advantage. With community financing, the supplies and services will usually be much more responsive to real local needs.

Impact -- Will tend to shift expenditures towards community demands. Often results in great increase in community's understanding and commitment related to program objectives.

Feasibility -- Start-up often requires very active outside education and encouragement to catalyze local interest. Experience in many different country settings has demonstrated that limited community financial support is almost always feasible.

(6) Insurance

Equity -- Insurance, of course, is not a "source" of financing but a mechanism for spreading financial risk, and therefore will usually be considered more equitable than individual payment as need arises. Depending on the source of payment for insurance premiums (individual, employer, government, etc.) there may also be a sharing of costs by those outside the group being covered.

Efficiency -- Varies widely, depending on costs of administering the scheme, profit of insurance carrier, if any, and whether private drug supply channels are used. In general, insurance schemes can be expected to add cost in order to spread risk and increase equity.

Stability -- Depends on stability of insurer, which varies.

Flexibility -- Depends on terms of insurance coverage. Plan always puts some limitations on what it will cover, but generally very flexible within this constraint. May also allow flexibility to obtain drug supply from private pharmacies with reimbursement, but this is rare in developing countries. More often, clients must obtain supplies at certain specified outlets.

Impact -- Depends on terms. Prepaid health coverage generally motivates increased consumption of health services, unless providers are motivated to reduce consumption, or supplies are simply unavailable.

Feasibility -- Administrative requirements of insurance plans are formidable. If these are not present in the private sector, Government will generally not be well advised to consider establishing a plan, unless general political or economic considerations indicate a necessity to do so. When they exist already, their drug supply provisions may be expanded to take advantage of the positive aspect of insurance -- protection for individuals against risk of large unanticipated expenses.

(7) Individual Consumer Expenditure

Most countries and programs find the options outlined above desirable, in that the costs of drugs and health care are not felt directly by the individuals in need. Unfortunately, those options are usually not adequate to meet all of the need for health services. It is thus almost invariably necessary to require a portion of drug and other health care costs to be borne directly by consumers, in a "fee-for-service" system, if access to care is to be made available to all.

Equity -- Although the previous options attempt to spread costs toward the population at large, or toward certain segments with greater ability to pay, this may be an illusion. The fact remains that, except for foreign donors or local charities, it is the individuals in the country who actually pay. Overall costs are still borne in large measure by those receiving the services. Thus, the difference in equity between the other financing options and fee-for-service is not as great as it might seem.

Efficiency -- Individual payments can be highly efficient, because the administrative costs of collecting and redistributing funds are avoided. However, this can be offset by the need to handle and record money transactions at the field level unless simple and effective schemes are developed to minimize this burden.

Stability -- Because the spending power of individuals is tapped directly the system is basically self supporting. Therefore, unless the economy as a whole deteriorates badly, the supply of drugs can be financed indefinitely.

Flexibility -- Highly flexible, since consumers themselves decide what and when they will purchase.

Impact -- Can be expected to have a definite impact on the pattern of drug utilization, with sharp increase in consumption of drugs with high immediate value (real or perceived), and decreased utilization of preventive medicines, etc.

Although one might expect that charging for drugs rather than giving them away free would result in a strong decline in consumption, data from many countries indicate the opposite. If virtually unlimited quantities of

Country Study III.E.2.

Financing in Selected Countries

Papua New Guinea -- Health services are financed by funds from the national budget and contributions of goods and services through missions and other charitable organizations. The Chief of the Pharmaceutical Services Section (PSS) estimates that slightly over half of the U.S.$4.5 million spent by the health care section is on pharmaceuticals. Although there is a nominal fee of U.S.$0.15 - 0.75 per outpatient visit, there is no drug or dispensing fee as such.

The Base Medical Stores order and distribute pharmaceuticals on the basis of demand. Overall expenditures are kept near (although usually 10-15% above) the nationally budgeted amount by the Chief of PSS, who continually seeks the lowest cost suppliers and holds back on less essential items. Base Medical Stores and hospitals are forced to budget themselves on the basis of the drugs which are made available by PSS Headquarters. (1978)

Malaysia -- Drugs are distributed without charge to patients seen in the government health services. A small visit fee may be charged, but the fee is not for drugs as such and is not influenced by the number or amount of drugs prescribed. Nevertheless, there is a strict costing and accounting system. Each State has a drug budget, and drugs supplied to the States by the Government Medical Stores (GMS) are charged against the budget.

For drugs purchased in finished dose form, the states are billed at the acquisition price. The accounting department maintains an average cost for each item, which is updated as the acquisition price changes. Drugs manufactured by the government are charged to the States at a price equal to the materials cost plus 10% for overhead.

Since health is a federal responsibility, payment procedures are handled at the federal level. State allocations for drugs are kept in the Ministry of Health treasury and simply transferred to the GMS, where a record is maintained of all receipts and issues. The record of the purchase costs is used for billing purposes and a copy is sent to the State Pharmacy for its records.

Distribution of drugs is the responsibility of the States, so distribution costs come out of the State budgets. In one State, for example, the cost of operating the medical stores and vehicles is about U.S.$90,000 per year for purchases of U.S.$1 million in drugs and U.S.$600,000 in medical supplies. In other words, the distribution costs are about 5-1/2% of the acquisition costs. (1978)

Tanzania -- Drugs are distributed without charge to patients. They are paid for out of the Ministry of Health budget. A total drug allocation is divided among the 20 mainland regions and 5 Zanzibar regions. Initially a U.S.$1.28 million revolving capital fund was established for the Central Medical Stores (CMS). Funds allocated for drugs were originally transferred to the regions who were then billed periodically and in turn transferred funds back to the medical store. The difficulty was that the regions were behind in repaying the CMS, either because of cash flow problems or because of over-expenditure in other categories.

The system has since been changed so that the funds allocated for each region's drugs are deposited directly into the CMS accounts. However, the regions are ordering beyond their allocations and the CMS is obligated to fill the orders if it has the stock. For the first 3/4 of the fiscal year 1977/1978, the 20 mainland districts had been issued about U.S.$10 million on a budget of U.S.$7.2 million. Seventeen of the 20 districts were in the red and only 3 in the black.

Theoretically, the users are billed the C.I.F. price plus a small percentage. However, the C.I.F. price changes from one purchase order to the next and the adjustment in the regional price does not seem to keep up with these changes. It appears that regions not only overrun their budget, but their accounts are also undercharged. Thus, it would seem that demand substantially outweighs supply. (1978)

Peru -- For each drug supplied by the Basic Medicines Program, a selling price is established which is, on the average, 20% above the purchase price. This 20% margin is split 50-50 between the various government agencies using the drugs (military, police, and others) and the Basic Medicine Program, except in the case of the Ministry of Health, where 100% is returned to the Ministry. This income is intended to make the Program self-sufficient in terms of administrative costs. (While the difference between purchase price and selling price averages 20%, it ranges from 0 to 40%. Expensive products imported in finished dose forms -- insulin, blood products, etc. -- have little or no markup.)

The selling price is established so that participating agencies can sell the medicines to their patients. Some users, however, provide all Basic Medicines without charge as part of contracts or institutional policy. All patients served by the Ministry of Health through its hospitals, centers, and health posts are charged the public price. However, those who cannot afford to pay for the medicines are generally given the medicines for little or nothing. The cost of medicines given away may be borne by the local community or be taken from the hospital budget. (1978)

low-cost, good-quality drugs are made available, even those with the lowest incomes will have greater access than with a policy of free distribution of a small supply.

Feasibility -- Experience in a variety of national settings confirms that low-cost drug sales programs are feasible in practical terms. The biggest single obstacle is political feasibility. We would stress that establishing an on-going self-supporting drug supply system should not be ruled out until needs have been fully understood and the alternatives considered.

c. Choosing a Funding Strategy

It is hard to imagine a national drug supply program that relies exclusively on one or another of the above alternatives. A program has a variety of service channels, supplies many segments of the population, and offers drugs which address different health problems. A well-designed financing strategy will carefully tailor available financial sources to the channels, segments, and products to which they are best suited. Country Study III.E.2. describes the financing patterns in selected countries.

Figure III.E.5. summarizes this analysis of drug supply financing alternatives. The most important conclusion from the analysis is that each alternative has strengths and weaknesses and merits serious consideration. In general, the costs of assuming universal access to basic health care are so enormous that most countries will not simply be picking and choosing, but will be struggling to derive every measure of support possible, and tailoring the resulting package to the program's needs.

4. DRUG SALES PROGRAMS

One financing option which is of special interest is the sale of drugs to patients through health facilities. Individual consumer expenditure for drugs has gained increased acceptance from Ministries of Health, as they realize that their commitment to free curative care may seriously bias expenditures away from much more cost-effective public health interventions, such as mass immunization against childhood diseases. Some of these same ministries are now experimenting with ways of getting the public to pay for part of their curative care, while ministry funds are directed towards interventions that will have more impact on priority morbidity and mortality indicators. Examples of two government drug sales programs appear in Country Study III.E.3.

Drug sales programs are relatively easy mechanisms for raising the public's contribution to curative care. Reasons for this are noted below:

- The public is already accustomed to paying for drugs in the private sect
- It is fairly easy to calculate the cost of delivering drugs in the healt care system, providing an easily understood rationale for the prices charged.

Country Study III.E.3.

Two Government-Sponsored Sales Programs

Afghanistan -- Drugs distributed by Village Health Workers in rural areas were sold. The price was based on the UNICEF catalogue price (UNICEF provided the initial supply under its assistance program) plus 15 percent to cover shipping. Approximately U.S.$0.005 was added to cover the cost of the label and plastic bag used in the course-of-treatment packaging. The total was rounded off upward to the next whole afghani (forty afghanis equalled one U.S. dollar), except in the case of oral rehydration salts which were rounded down to the next whole afghani. This "discount" was to encourage use of this life-saving but relatively unfamiliar and unpopular intervention. U.S.$0.05 was added to these costs to provide income for the Village Health Worker.

No attempt was made to recover all packaging costs, the remainder of which were borne by the Ministry of Health and foreign assistance sources. Similarly, the Ministry bore all costs incurred in storing and delivering the drugs to the Basic Health Center closest to the Village Health Worker. The Village Health Worker travelled at his own expense to the Basic Health Center to purchase resupplies with the money collected from the sale of his initial stock, which was provided free of charge upon completion of his training. The following table shows prices charged by the Village Health Worker per course-of-treatment.

Drug	Quantity per Course-of-Therapy	U.S.$ Price per Course-of-Therapy
Aspirin, 500 mg.	9 tablets	$0.10
Aspirin, 150 mg.	9 tablets	0.075
Multivitamins with iron and folate	30 tablets	0.125
Oral Rehydration Salts (pkt. for 1 ltr.)	1 sachet	0.25
Iron with folate, adult dosage	90 tablets	0.20
Iron with folate, child dosage	30 tablets	0.10
Piperazine, adult dosage	14 tablets	0.15
Piperazine, child dosage	6 tablets	0.10
Tetracycline eye ointment, 5 gram tube	1 tube	0.175
Penicillin, adult dosage	30 tablets	0.49
Penicillin, child dosage	15 tablets	0.325

Sales data showed that the average patient who purchased drugs from a Village Health Worker paid U.S.$0.21 for his drugs. This compared very favorably with survey data which showed the average purchase from a rural pharmacy to be U.S.$6.20. It should be noted, however, that the Ministry of Health was subsidizing the program and also that the profit margin allowed to the Village Health Worker was not sufficient to serve as much of a financial incentive. In fact, several Village Health Workers reported using their profit to hand free distribution of drugs to those who were unable to pay. (1978)

Haiti -- The drug sales program in Haiti has not yet been implemented. The primary objective of the program will be to recover all direct costs associated with the distribution of each course-of-treatment. Various subsidy and surcharge policies are under consideration, but have not yet been decided upon. Detailed cost estimates for the drug supply system have, however, been worked out. The following table shows the tentative course-of-treatment and anticipated cost for a few of the fifty to sixty drugs to be included in the program.

Drug	Quantity per Course-of-Therapy	U.S.$ Price per Course-of-Therapy
Aspirin, adult	20 tablets	$0.10
Aspirin, child	10 tablets	0.05
Piperazine, adult	5 tablets	0.05
Piperazine, child	3 doses syrup	0.03
Penicillin V, adult	30 tablets	1.62
Penicillin V, child	15 tablets	0.81
Multivitamins	30 tablets	0.24
Iron with folate, adult	90 tablets	0.31
Iron with folate, child	30 tablets	0.11
Tetracycline eye ointment 5 gr. tube	1 tube	0.30
Oral Rehydration Salts	2 sachets	0.48

(1981)

- Through bulk procurement of drugs by medical (generic) name, the Ministr can frequently recover all its costs and still under-price private sector drugs, enabling it to pass substantial savings on to the patient.

- Enormous flexibility exists, permitting the subsidy of certain drugs suc as vaccines, while taxing the consumption of non-essential drugs through price surcharges.

a. Drug Pricing

Figure III.E.6. lists the major components which should be considered in an attempt to recover drug supply system costs through a drug sales program. The percentages adjacent to each component will vary widely from system to system depending on the degree to which "Drug Costs" have been minimized, on the efficiency of the system, and on geographic and demographic factors, e.g., population density, which are beyond the system's control. The percentages shown in the table are those estimated as necessary to recover costs in a government-sponsored community pharmacy program.

In this system, operating costs are estimated to be 110% of drug acquisition costs; therefore, the price of a drug would be -- on the average -- 210% of its purchase price. In our experience, the total of procurement and distribution costs ranges from 20 to over 100% of the drug acquisition costs, depending on the economy with which drug purchases are made and the efficiency with which procurement and distribution functions are performed.

Figure III.E.6.

Components of Price in a Proposed Drug Sales Program

Component	Approximate % of Drug Cost
1. Course-of-Therapy Packaging	10%
2. Operating Costs of Drug Supply System	50%
3. Inflation (18 month pipeline)	20%
4. Wastage	30%
5. Development Costs (Amortization)	*
Total Projected Markup Above Drug Procurement Cost	110%

* In the proposed program no markup has been included for the recovery of development costs.

As mentioned above, not all drugs need to be marked up equally. The VEN (vital, essential, non-essential) system discussed in Chapter VI.B. can be applied to pricing schemes very easily. Suppose that in addition to the vital, essential, and non-essential categories, drugs were also classified as preventive and curative. The resulting six categories can be represented by a 2 x 3 rectangular matrix. (See Figure III.E.7.) All the drugs included in the drug sales program should be assigned to one of the six categories. By multiplying the anticipated consumption of each drug by its unit cost and adding these costs together for all drugs in each category, a figure is reached by which each category can be weighted.

Figure III.E.7.

Application of VEN to a Drug Sales Program

Drug Classification

	VITAL		ESSENTIAL		NON-ESSENTIAL	
PREVENTIVE	DRUG No.1	$1,000	DRUG No.3	$1,000	DRUG No. 4	$1,500
	DRUG No.2	2,000				
		$3,000		$1,000		$1,500
CURATIVE	DRUG No.5	$4,000	DRUG No.8	$1,500	DRUG No.10	$2,000
	DRUG No.6	2,000	DRUG No.9	3,000	DRUG No.11	1,000
	DRUG No.7	2,500		$4,500	DRUG No.12	1,500
		$8,500				$4,500

Subsidy and Surcharge Allocation

	VITAL	ESSENTIAL	NON-ESSENTIAL
PREVENTIVE	Total Cost $3,000 Subsidy Rate: 100% Total Subsidy.....$3,000	Total Cost $1,000 Subsidy Rate: 50% Total Subsidy.....$500	Total Cost $1,500 Subsidy Rate: 33% Total Subsidy.....$500
CURATIVE	Total Cost $8,500 Surcharge Rate: 10% Total Surcharge...$ 850	Total Cost $4,500 Surcharge Rate: 20% Total Surcharge...$ 900	Total Cost $4,500 Surcharge Rate: 50% Total Surcharge...$2,250

Next, the different categories should be prioritized according to whether the category should be subsidized or a surcharge added. The amount of subsidy or surcharge would depend upon program policy. Generally, preventive drugs, except those in the non-essential category, would be subsidized to encourage the use of these cost-effective drugs which are not in great demand; a surcharge would be levied on curative drugs, especially those in the essential and non-essential categories. To recover 100 per cent of costs, care must be taken to recover the total of all subsidies by an equal total of surcharges. Figure III.E.7. is a hypothetical illustration of how this system works.

There are many other criteria and policies which can be applied using the methodology illustrated in Figure III.E.7. It might be government policy to finance all preventive drugs out of the national budget and foreign assistance, while subsidizing the sale of vital drugs with a surcharge on non-essential drugs. Or a surcharge on non-essential drugs might be used to finance limited free distribution of vital drugs to indigents. The important point is that a government's drug pricing policy can serve two important objectives, in addition to supplementing the government's health budget.

(1) Surcharges on low priority drugs can be used to subsidize and, thereby, encourage the consumption of more cost-effective drugs.

(2) Surcharges levied on drugs can be used to subsidize distribution to indigents or other priority population groups such as infants and young children.

b. Revolving Drug Funds and the Pipeline Concept

Drug sales programs, in which consumer contribution covers the cost of drugs received, are frequently conceptualized as "revolving funds". Start-up money is provided to purchase an initial supply of drugs which are then sold. The proceeds from the sale are used to purchase replacement stocks which are in turn sold. The cycle can be repeated indefinitely without further government allocations as long as the funds recovered from sales are sufficient to purchase replacement stock.

Revolving funds are attractive because they are theoretically self-financing, once start-up funds have been provided. They are particularly popular with foreign aid donors because they do not require a lengthy analysis of the recipient government's ability to maintain the project; the system is financially closed and should require no injections of funding from the government or outside to keep them going.

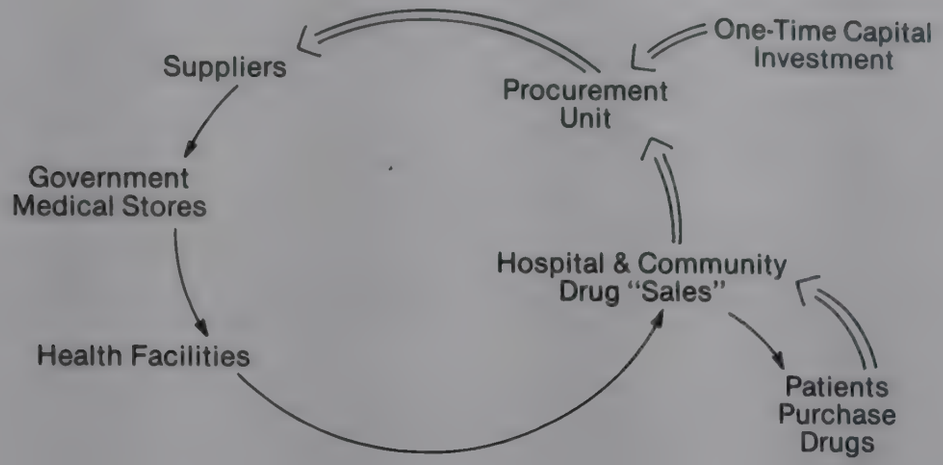
Common Weakspots in Planning Revolving Funds

Despite the practical appeal of revolving drug funds in theory, there are several weakspots which repeatedly occur in practice. The result of these weakspots is that the ideal situation -- where expenses equal receipts during each time period after the initial start-up -- is not realized. Too often, expenses and other losses greatly exceed receipts; the fund gradually shrinks and, in essence, ceases to rotate (Figure III.E.8.). Country Study III.E.4.

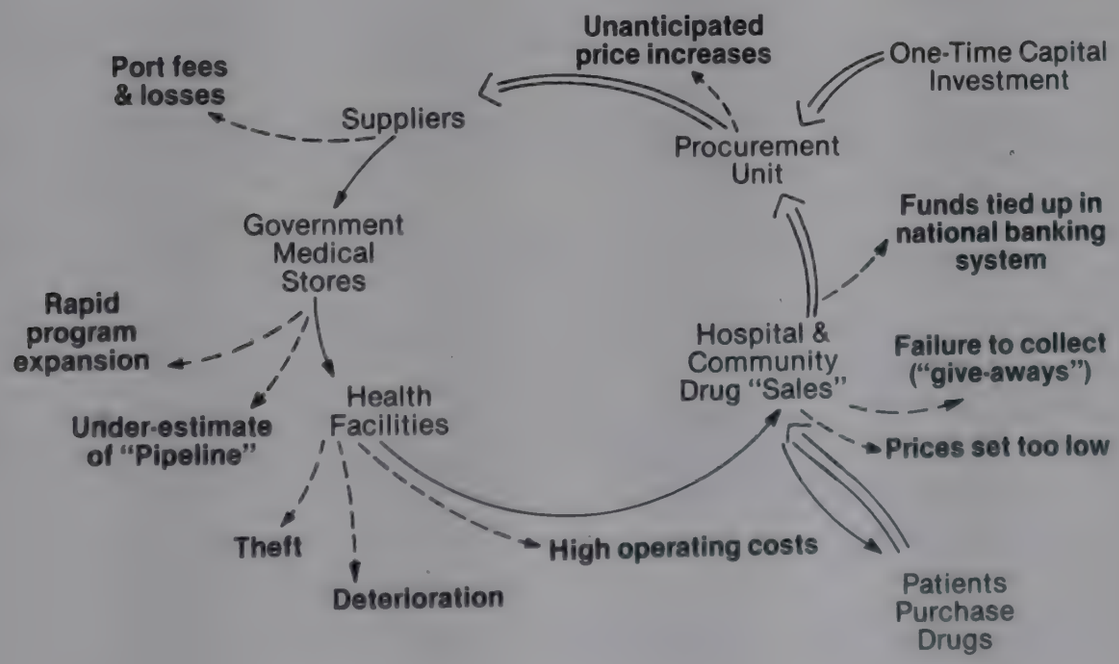
Figure III.E.8.

Revolving Drug Funds in Theory and in Practice

IN THEORY—EXPENSES FOR EACH CYCLE **EQUAL** RECEIPTS:



IN PRACTICE—EXPENSES FOR EACH CYCLE, INCLUDING LOSSES, **EXCEED** RECEIPTS:



Key:
- Flow of drug supplies
- Flow of funds
- Loss of available funds or drugs

Country Study III.E.4.

Revolving Fund for Drug Sales in Rural South America

The Ministry of Public Health and a bilateral aid program started the Montero Project in Rural Health in 1976. Initially the Project emphasized demographic and epidemiological research, but gradually it changed its objectives to being an area demonstration project aimed at developing a model for rural health services delivery.

The Project developed a list of 19 basic drugs that auxiliary health workers would sell in the course of providing health services. The money from sales would flow into a revolving fund from which the Project would purchase new stock, thus being self-sufficient for pharmaceutical supplies. The Project viewed community organization as a precondition to achieving acceptable levels of service. The communities, through health committees, would provide both support and some supervision to both auxiliary nurses and health promoters. The Project strongly promoted the view that it was furnishing supplies to the communities themselves for use by the health workers in the performance of their duties.

A bilateral aid program assisted by providing contributions of drugs. The Project was to sell them, using the proceeds to start up the revolving fund. The Project assumed responsibility for financial management, procurement, storage, and distribution of the drugs. In August, 1976, the Project opened a bank account, distributed initial stocks to communities, and began selling drugs. At its height, the sales program was supplying 50 health workers, serving a population estimated at 10,000.

Although the conceptual basis and objectives of the Montero Project drug sales program were sound, the Project was not successful. The plan called for auxiliaries to purchase supplies on a monthly basis for their Basic Health Unit (health post and health promoters serving a specific community). An analysis made in May, 1979, showed that between August, 1976, and that date, the project had expanded to include eleven Basic Health Units. Some of these had participated as long as thirty-three months and others as few as six months. Given the total number of participation months for each Basic Health Unit, the Project should have made 241 separate monthly sales. In fact, only 17 took place and the money recovered was only a fraction of the replacement cost of the drugs the Project had distributed. By May, 1979, drug supplies at the central level were depleted and the sales program was at a standstill.

Supply system records were incomplete and disorganized. It was not possible to extract reliable information on the quantities of drugs the Project had received and distributed. A number of obvious "leaks" could be identified, but available information was insufficient to determine the relative significance of each in the decapitalization process.

The problems listed below were the most important contributors to the failure of the revolving fund. These are not unique to the Montero Project, and all have been observed in comparable programs in other countries:

- Project staff did not understand the need to maintain reserve stocks. Too many drugs were distributed in an ambitious startup and not enough were held in reserve. When auxiliaries came to buy fresh drugs there was little left to sell them.

- Stock levels were not adjusted to actual consumption. Many health posts had large surpluses of drugs that other posts were unable to obtain because they were out of stock at the central level.

- Growth in the demand for drugs was not anticipated. Increasing volumes of drugs were sold for which there was insufficient time to replenish supplies.

- There was confusion over the "ownership" status of the initial stocks. Strictly speaking, drugs were consignments for sale. The indiscriminate use of the word "donation" led some communities to regard the drugs as outright gifts. With this in mind, they declined to turn over money from sales when the project could not supply fresh drugs.

- Drug prices did not reflect replacement costs. The role of inflation was not considered. Prices to the Basic Health Units were set too low to enable the Project to replace the drugs it sold.

- The main storage facility was woefully inadequate. Filthy and damp, it was insecure from both pests and people. A substantial loss of stock to spoilage is certain; losses from theft highly probable.

- The project packaged its drugs in paper envelopes and cartons. In humidity this did not offer sufficient protection, and much stock deteriorated beyond recognition before health workers could sell it.

In summary, the Montero Project's revolving fund appears to have fallen victim to just about every possible means of decapitalization. This, perhaps, suggests the underlying difficulty: project management greatly underestimated the level of effort and detailed planning required to design, implement, and maintain a revolving fund drug sales program.

ells the unfortunately common story of a revolving drug fund which failed. The most significant weakspots in revolving drug funds are the following:

(1) Leakage -- Leakage occurs if drugs are underpriced relative to their cost. The costs of drug supply have been discussed in detail earlier in this chapter. All costs that are not recovered through sales must be met from other funding sources, or the amount which can be purchased during each successive cycle will continually decrease.

(2) Foreign Exchange -- Sales revenues will be collected in local currency. Imported drugs, however, may have to be purchased with foreign exchange, which is in scarce supply in some countries. Foreign exchange shortages may "break" the cycle on the "funds" side, preventing procurement of replacement stocks.

(3) Underestimation of Capitalization Requirements -- The period of time from initial commitment of funds until the corresponding commitment of funds for replacement stocks, times the volume of sales per unit of time, equals the amount of capital needed to fill the pipeline. Frequently the length of time required to make one complete revolution is grossly underestimated. As a general rule of thumb, it is more likely to be over 2 years than under 1 year.

(4) Rapid Program Expansion -- In a program which is expanding rapidly, sales will continue to appear small compared to demand for increased capital. For example, suppose a small pilot project is being expanded nationally, and during the rapid expansion phase the number of health workers supplied by a revolving fund triples each year starting with 10 in year 1. Suppose the pipleline is a modest 2 years. In this example, 90 units of supply must be ordered in year 1 at a time when only 10 units of sales are being generated. In year 2, 270 units of supply must be ordered while sales represent only 30 units. An expanding revolving fund requires an expanding capital base. It will not become independent of outside injections of capital until expansion is complete.

Estimating the Pipeline

In assessing the capital requirements of a revolving fund it is useful to hink of the drug supply system as a pipeline. In order to assure a continuous upply of drugs at health service facilities, the pipeline must be filled; once illed, consumption must be matched by purchases at the other end. Filling the ipeline is a development cost. It is an investment in the inventory required o assure continuous satisfactory drug deliveries to health service facilities. n the case of revolving funds, the investment must also include financial reerves (inventory) in the form of letters of credit and bank accounts where evenues from drug sales are "stored" until purchases are made.

To estimate the development expenditure necessary to capitalize the drug upply system, two variables are important. First, the rate of consumption ust be estimated in specific terms, for example, "100 ampules of DPT per onth per health facility." Estimation of consumption rates was discussed in hapter II.B. Second, the length of the pipeline, or the time required for

one complete cycle of the revolving fund, must be estimated. This involves a detailed understanding of the route followed by the drugs from manufacturer to patient, and the corresponding flow of funds from patient to manufacturer. The amount of time spent by drugs or money at each stage should be estimated. Then, the total time spent in all stages is the length of the pipeline. A list and description of the principal stages in a revolving fund cycle follow. The calculations for a typical fund appear in Country Study III.E.5.

(1) Procurement -- Frequently the purchaser must produce a letter of credit before a manufacturer will prepare a consignment for shipping. Funds may thus be "tied up" a month or more before the manufacturer actually ships the drugs.

(2) Transportation -- Imported drugs may spend 6 months or more in transit between the manufacturer's warehouse and the receiving facility in the drug supply system. Time spent in customs and port-clearing should be included. This segment of the pipeline will generally be much shorter for domestically produced drugs.

(3) Repackaging -- Once the drugs have been received at the central warehouse of the drug supply system, they may have to be repackaged before they are ready for shipment to health service facilities. Course-of-therapy packaging has several advantages in encouraging proper use of drugs and is discussed in later chapters. Even if course-of-therapy packaging is not incorporated into the system, relabeling of drugs in local languages may be required. Time must be included in the pipeline for any repackaging or other processing the drugs must undergo.

In the case where repackaging is a function of the drug supply system itself, i.e., it is not subcontracted out, the output of the repackaging unit may be both reliable and flexible. Flexibility requires that additional unskilled labor can be hired on a daily basis to respond to unanticipated demand. In this case, repackaging may not add significant to the length of the pipeline, since the process may occur while the drugs are in safety stock, held at the central warehouse to cover uncertainty in delivery schedules.

In instances where repackaging is subcontracted to the private sector, special allowance should be made for the time between delivery of the drugs to the contractor and receipt of the repackaged drugs. In this case safety stocks should be held in the form of repackaged drugs, and would also depend upon the dependability of the contractor to meet delivery schedules and to respond to changes in demand.

(4) Warehouse Inventories -- It is convenient to divide warehouse inventories into working and safety stocks. Working stocks should vary according to where one is in the procurement process. (Unlike oil in a pipeline, drug shipments are "lumpy", i.e., in a system that makes quarterly procurements of penicillin V, a three months' supply will be received all at once.) On the day a shipment is received, working stocks should be at a maximum. Ideally, on the day before, working stocks should have been reduced to zero. The average amount of working stock on hand equals one-half the regular procurement volume; thus, in the case

of quarterly procurements, working inventory equals 1/2 of 3 months' consumption, or 1-1/2 months' consumption. (See Chapter IV.B. for further details on inventory quantities.)

In addition to working inventories, safety stocks are also required. Safety stocks are used to insure against uncertainties in supply and demand. Generally, at the central warehouse level, uncertainties of supply will dominate. Surface shipments of drugs from UNIPAC to Afghanistan could spend a year or more in transit, although "normal" transit time was alleged to be 6 months. At the health facility, variations in demand may present a greater problem. For example, one village health worker may exhaust a three-month supply of piperazine in 2 days after having spectacular and highly visible success in treating a young girl with an infestation of ascaris. At the central level, these fluctuations in demand tend to "average out" over a large number of facilites.

There is no handy rule of thumb by which the size of required safety stocks can be estimated a priori. This is particularly true in the case of new or reorganized drug supply systems where procurement routines are not well established, resulting in supply uncertainties, and where consumption estimates are based on theoretical guesses rather than experience, resulting in demand uncertainties. In general, new supply systems should probably contain safety stocks equal to at least 6 months' consumption.

Finally, working and safety stocks are necessary at each level in the drug supply system: central warehouse, regional and/or district depots, and health service facilities. The working stock at each level depends on the standard supply interval for the level in question. The safety stock held at each level will depend upon uncertainties in supply and demand and also the relative cost of obtaining an emergency shipment should a stockout occur. Special shipments or transfers between storage points are generally easier to effect the lower one is in the system.

(5) Revenue Accumulation -- This stage in revolving funds is frequently forgotten. It should be included. Several months may elapse from the time a patient pays U.S.$0.35 for a course-of-therapy of iron tablets, until that U.S.$0.35 has been deposited in a bank account and that account has accumulated sufficient funds to cover a letter of credit. Where average order size is large relative to total revolving fund assets, funds will spend relatively longer sitting idle in bank accounts. If procurements are made independently and periodically according to a routine schedule, money in the bank can be treated in the same way as working stock. If the average purchase is equivalent to a 3 month supply, the average dollar will spend 1-1/2 months in the bank before being committed in a letter of credit.

If, on the other hand, procurements are routinized through contracts with suppliers to ship drugs in fixed quantities on a pre-arranged schedule, it may be necessary to maintain a safety stock in monetary form. This safety stock exists in the form of an average minimum balance at the bank which is used to cover commitments to manufacturers during periods when revenues are less than anticipated.

Country Study III.E.5.

Pipeline for a Proposed Drug Sales Program in Haiti

Experience in Haiti suggests that the Ministry of Health will, in the foreseeable future, have the financial resources to provide all needed drugs to all of the people all of the time. Furthermore, there is evidence that many patients would be willing to pay a reasonable fee for drugs, rather than go without drugs, in a system of free supply plagued by chronic stockouts. Therefore, the Government of Haiti is seriously considering setting up a self-financing drug sales program to supplement the free distribution program. Main features of the proposed program include:

- Formation of a semi-autonomous agency to procure, store, package, and distribute drugs for sale through autonomous, but regulated and supervised, community pharmacies.
- Establishment of independently operated community pharmacies located in each Ministry of Health facility to stock and sell the complete range of drugs appropriate for the associated facility.
- Continuation of free distribution of priority drugs, particularly preventive drugs and vaccines, through Ministry facilities, with an attempt to restrict free distribution to those unable to pay. The Ministry will purchase these drugs from the central warehouse of the semi-autonomous agency on a cash-and-carry basis.
- Setting a pricing policy at the central level that attempts to recover all costs associated with the drugs being sold, and may include markups to cover inflation and part or all of the costs of the free drug distribution program.
- Course-of-therapy packaging for all tablets and capsules sold through the community pharmacies.
- Systematic selection of a limited number of basic drugs, chosen from epidemiologic studies, to cover the major illnesses prevalent in Haiti.

The pipeline for the proposed drug sales program is defined as covering the period of time elapsing between the disbursement of funds for a purchase to the disbursement of the funds collected from the sale of that purchase. Based on current proposals and assumptions, the pipeline can be broken down into a number of segments, described below and illustrated in the accompanying diagram.

1. Foreign Purchase Pipeline (6 months) -- One half of the pharmaceuticals will be purchased from foreign sources. On average 6 months will elapse between the provision of a letter of credit and the receipt of the pharmaceuticals at the Central Warehouse of the semi-autonomous agency after clearing customs.

2. Domestic Purchase Pipeline (1 month) -- One half of the pharmaceuticals will be purchased from local sources. On average, 1/2 the payment will have to be made 2 months in advance of their receipt, with the balance paid upon receipt.

3. Central Warehouse Safety Stock (6 months) -- A six-month safety stock will be maintained at the Central Warehouse.

4. Central Warehouse Working Stock (3 months) -- The semi-autonomous agency will place orders for each item two times per year. This implies a maximum working stock of 6 months and an average working stock of 3 months.

5. Regional or District Safety Stock (2 months) -- The regional or district storerooms of the semi-autonomous agency will maintain a two-month safety stock.

6. Regional or District Working Stock (1 month) -- The regional or district storerooms will receive shipments from the Central Warehouse every 2 months, implying a maximum working stock of 2 months and an average working stock of 1 month.

7. Community Pharmacy Safety Stock (1 month) -- The community pharmacies will maintain a one-month safety stock.

8. Community Pharmacy Working Stock (0.5 month) -- The community pharmacies will be resupplied once per month, implying a maximum working stock of 1 month and an average working stock of one-half month.

9. Communities Pharmacy Cash-on-Hand (0.5 month) -- The community pharmacies will turn in their revenues once per month when they purchase their resupplies from the regional or district storerooms. On average these funds will have been held 1/2 month by the community pharmacies.

10. Region or District to Center Cash Transfer (1 month) -- Money received by the regional or district storerooms will be deposited within the week at the local branch of the national bank. On average it will take 1 month for this money to be credited to the account of the semi-autonomous agency in Port-au-Prince.

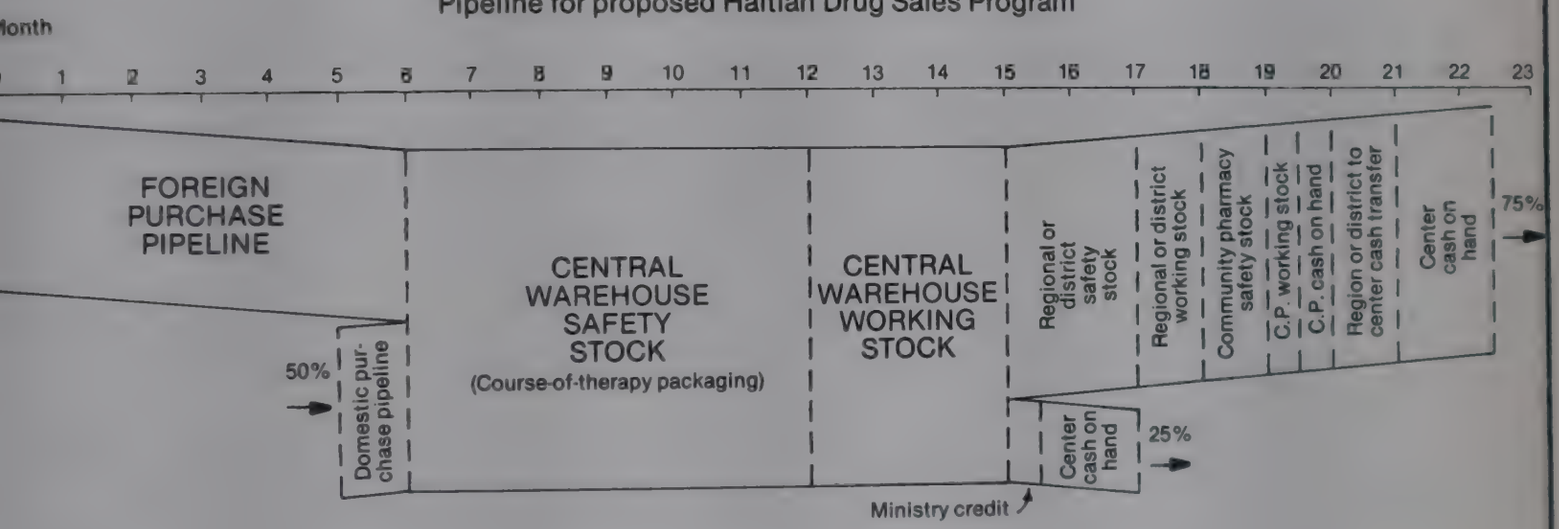
1. Center Cash-on-Hand (1.5 months) -- In general, purchases made by the semi-autonomous agency will be arge, representing one-fourth of its annual turnover. As a result, money will sit in the agency's entral account up to three months, or an average of 1-1/2 months, before being used to effect a purchase.

2. Ministry Credit (0.5 month) -- About one-fourth of the semi-autonomous agency's sales will be made irectly to the Ministry. The Ministry will pay within one month of receipt of the drugs, or on average fter 1/2 month. The money will be deposited directly in the agency's central account. (Segments 5 hrough 10 of the pipeline will not apply in the case of sales to the Ministry.)

3. Course-of-Therapy Packaging -- The course-of-therapy packaging will take place at the Central Warehouse nd will operate on the safety stock held there. The large "safety" stock at the central warehouse will herefore consist of bulk packaged drugs, drugs in process of course-of-therapy packaging, and course-of-herapy packaged drugs ready for distribution. The process of course-of-therapy packaging has therefore ot added to the length of the pipeline, although without it a smaller safety stock might be sufficient at he central warehouse.

he average length of the pipeline is calculated to be a little more than 18 months. A little more than ne and one half million dollars will be needed to fill the pipeline, when all 200 planned community harmacies are operational.

Pipeline for proposed Haitian Drug Sales Program


Month
0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23
FOREIGN PURCHASE PIPELINE
50%
Domestic purchase pipeline
CENTRAL WAREHOUSE SAFETY STOCK
(Course-of-therapy packaging)
CENTRAL WAREHOUSE WORKING STOCK
Regional or district safety stock
Regional or district working stock
Community pharmacy safety stock
C.P. working stock
C.P. cash on hand
Region or district to center cash transfer
Center cash on hand
75%
Center cash on hand
25%
Ministry credit

To Calculate Average Pipeline Length:

37.5% (0.5 x 0.75) are foreign-purchased drugs sold by community pharmacies: Pipeline = 22.5 months
12.5 % (0.5 x 0.25) are foreign-purchased drugs sold to Ministry of Health: Pipeline = 17.0 months
37.5% (0.5 x 0.75) are domestic-purchased drugs sold by community pharmacies: Pipeline = 17.5 months
12.5% (0.5 x 0.25) are domestic-purchased drugs sold to Ministry of Health: Pipeline = 12.0 months
Weighted average = [(0.375 x 22.5 months) + (0.125 x 17.0 months) + (0.375 x 17.5 months) + (0.125 x 12.0 months)] = 18.625 months

To Estimate Pipeline Capital Requirements:

Assume 130 community pharmacies associated with dispensaries have average monthly sales of U.S.$200.00
Assume 60 community pharmacies associated with health centers have average monthly sales of U.S.$500.00
Assume 10 community pharmacies associated with hospitals have average monthly sales of U.S.$600.00
Capital required = [($600 x 10) + ($500 x 60) + ($200 x 130)] = $62,000
[$62,000 + ($62,000 divided by 3)](sales to Ministry) x 18.625 = $1,540,000

Three Cautions for Estimating the Pipeline

There are three major sources of complications in estimating the length of the drug supply pipeline. First, different drugs may be obtained from different suppliers. Dependable domestic suppliers may be able to deliver quickly, although maybe at higher unit purchase prices than dependable foreign suppliers; foreign suppliers may be less expensive, but cannot control many of the variables involved in international transport. In general, delivery time will vary for each different supplier and will ordinarily be considerably longer for foreign suppliers.

Second, different types of purchasers may exist in the drug supply system. For example, the country's semi-autonomous national health insurance corporation may purchase drugs for its participants from the revolving fund. These purchases could be a significant fraction of total sales volume in the revolving fund. They would generally be made from the central warehouse and would not, therefore, involve all the intermediate stages of the supply system between central warehouse and rural health service facilities, or the tedious process of revenue collection.

Finally, as the demand for drugs expands, capital will be required to expand the capacity of the revolving fund. In general, if monthly sales increase by 20%, either because more health facilities have been added to the system or because more patients are being seen per facility, the total capitalization of the revolving fund must be increased proportionately. If it is not, safety stocks will be depleted and the number and frequency of stockouts will increase. When this happens service statistics will fall, including sales revenues, until the system is again in balance.

* * *

The drug supply pipeline is most accurately conceptualized as a branched pipeline. Various sources feed into the supply system, generally seen as starting at a central warehouse(s), and various users draw drugs out at points along the pipeline. To estimate the average pipeline length, then, each source and use must be weighted according to its share in total volume, as illustrated by the calculation in Country Study III.E.5.

SUMMARY

Expenditures on pharmaceuticals vary from over U.S.$35.00 per person in some developed countries to less than U.S.$0.50 in many developing countries. There is no standard amount that can be considered "sufficient" or "optimal", but extremely low expenditures on drug products are probably insufficient, even with efficient supply systems.

Three principle cost categories for drug supply are:

(1) Drug Costs -- Usually the major component, and certainly the component with the greatest foreign exchange implications.

(2) Operating Costs -- Funds for staff, facilities, vehicles, and other on-going expenses.

(3) Development Costs -- Often provided through foreign aid. Development expenditures have a large impact on future operating costs.

Financing options for public supply programs include:

- external (foreign) funding through grants and loans
- internal non-government sources (charitable organizations)
- national budget allocations
- regional, provincial or state budget allocations
- community contributions
- insurance (government, employee, individual)
- individual consumer purchase

These options may be compared and evaluated in terms of (1) equity, (2) efficiency, (3) stability, (4) flexibility, (5) impact, and (6) feasibility.

Drug sales programs offer a potentially adequate and self-sustaining source of revenue for supply programs. Revolving drug funds are attractive in many settings, but are fraught with weakspots. Common sources of failure in such funds are:

- leakage of funds from underpricing of drugs,
- foreign exchange controls which may restrict replenishment of supplies,
- underestimation of the pipeline, which results in inadequate stocking of clinical facilities,
- rapid program expansion, which consumes supplies too quickly to allow for their replenishment.

An important step in establishing a revolving drug fund is the estimation of the supply pipeline and acquisition of sufficient stock to fill this pipeline. Realistic provisions must be made for the undesirable, but inevitable, losses from the pipeline.

CHAPTER III.E. REFERENCES

Hay, L.E. and Mikesell, R.M.: Governmental Accounting. Homewood, Illinois: Richard B. Irwin, Inc., 1974.

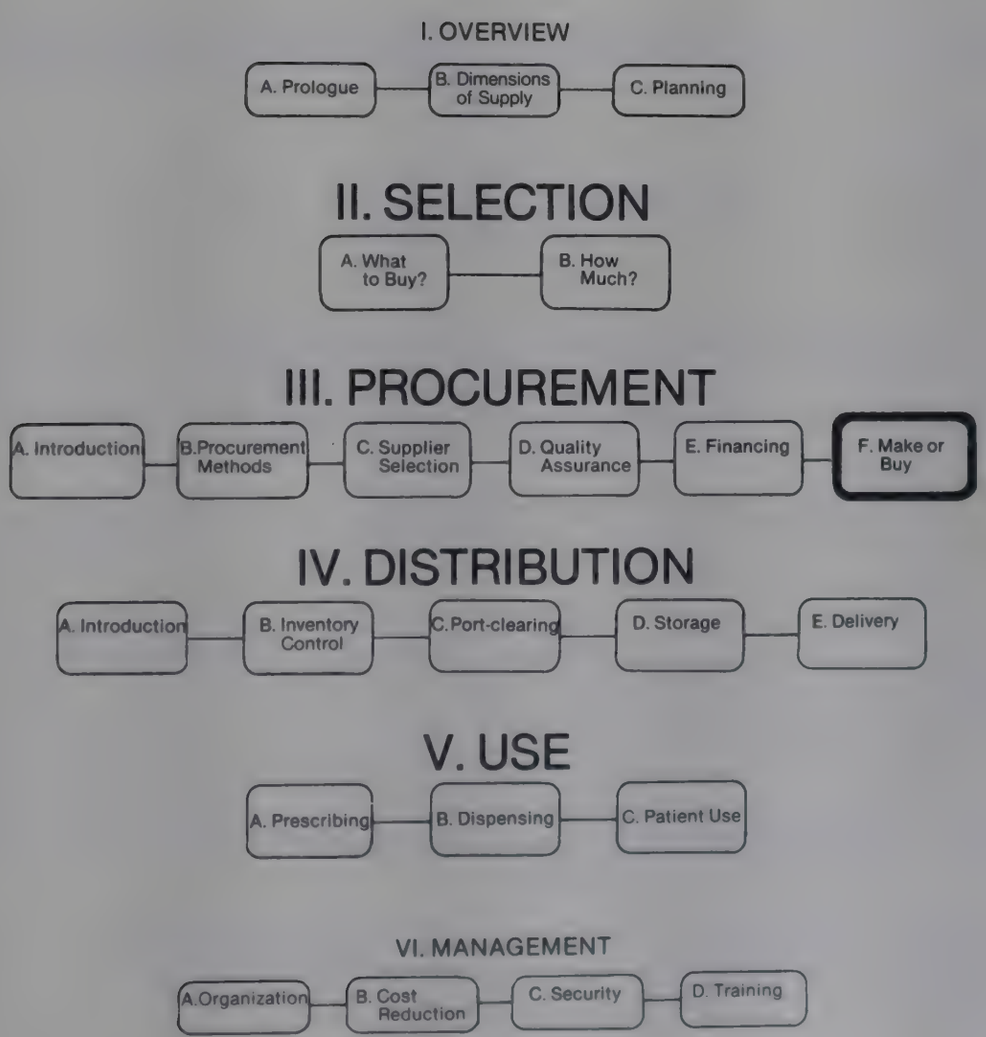
U.S. Department of Health, Education, and Welfare: Health Sector Financing in Developing Countries. Washington, D.C.: DHEW, International Health Planning Methods Series, No. 8, DHEW Publication No. (PHS) 79-50087, 1979.

World Health Organization: Expanded Programme on Immunization: Costing Guidelines. Geneva: World Health Organization, EPI/GEN/79/5, 1979.

Zschock, D.K.: Health Care Financing in Developing Countries. Washington, D.C.: American Public Health Association, International Health Programs Monograph Series, No. 1, 1979.

Chapter III.F.

Make or Buy: Local Production Opportunities



	Page
1. LEVELS OF PHARMACEUTICAL PRODUCTION	243
2. TO MANUFACTURE OR NOT TO MANUFACTURE	246
a. Primary Manufacture	247
b. Secondary Manufacture	249
c. Packaging	250
3. PREREQUISITES AND RESOURCES FOR PHARMACEUTICAL PRODUCTION	251
a. A Market	251
b. Manpower, Training, and Transfer of Technology	251
c. A Site for the Enterprise	252
d. Building	252
e. Finance	253
4. DETERMINING THE VIABILITY OF LOCAL PRODUCTION	253
5. IMPLEMENTING A PROGRAM FOR LOCAL PRODUCTION	256
Constraints and Prospects for Success	264
SUMMARY	264
REFERENCES	265
APPENDIX	
III.F.1. Sources of Technical Assistance for Local Production	267

Make or Buy: Local Production Opportunities

Whether drugs should be supplied solely by purchase of imported products or, at least in part, through local production is a complex decision which should be based mainly, albeit not exclusively, on economic factors. Although political pressures and the desire for national development can be potent influences and should be clearly recognized, they can lead a government to embark on projects which are economically or technically impractical and, thus, unsuccessful. Assessment Guide III.F. provides an introduction to the issues that will be considered in the following pages.

Interest in local production has grown considerably in recent years. But statements about national self-sufficiency, often politically motivated, are largely meaningless in the pharmaceutical arena, since all countries, large and small, find it either necessary or advantageous to buy some ingredients from foreign sources. No company, no industry, and almost no country is entirely self-sufficient. There are, nonetheless, many levels of production to consider that are appropriate in individual country settings.

Before examining local production alternatives, it will be useful to clarify the term, "pharmaceutical production".

1. LEVELS OF PHARMACEUTICAL PRODUCTION

Pharmaceutical production is a complex activity in which many interdependent manufacturing enterprises contribute to the production of a variety of pharmaceutical dosage forms. Production may be viewed in three essential phases:

Primary manufacture -- The production of active medicinal substances and other ancillary substances used in pharmaceutical formulations.

Secondary manufacture -- The processing of medicinal substances, usually together with ancillary substances, to produce the required pharmaceutical dosage forms. Other terms that are used to describe secondary manufacture are "pharmaceutical processing", a descriptive and non-ambiguous term, and "formulation", which is ambiguous since it is also used to describe the process of development of a pharmaceutical formula or "recipe". It is in this latter sense that the term "formulation" will be used here.

Packaging -- The packaging of dosage forms in manners appropriate to the nature of the preparations and their intended use, conditions of transportation, and expected conditions and time of storage.

These phases of manufacture may now be looked at in more detail. Figure III.F.1 summarizes the major categories of production and their subdivisions. It will be seen that primary manufacture includes organic, inorganic, physical, and biological processes. It usually involves complex operations which require highly skilled staff and highly specialized facilities. These technical requirements preclude primary manufacture for many countries.

ASSESSMENT GUIDE III.F.
Local Production Opportunities

Current Local Production

- What local government and non-government production facilities currently exist? Where are they located and who owns them? What products are currently produced locally and in what quantities are they produced?

- What kind of quality control is done by local production facilities? Is there an assessment of quality by an independent agency or laboratory? Generally, what is the quality of locally produced pharmaceutical products?

- What types of professional staff are employed at the facilities (industrial pharmacists, chemical engineers, industrial engineers, financial analysts, etc.)? Where do these professionals come from and how were they trained?

- What are the costs of local production? Are commercial producers making a profit? Are prices competitive with imports? For government production, what is the true cost of production? How does this cost compare with the cost of buying finished dose products through international tenders?

Potential Local Production

- Are there high-consumption and relatively simply-made products purchased which could be more economically produced locally?

- Do the necessary resources exist for local production, including energy sources, clean water, a suitable site, skilled laborers, and such?

- Is there sufficient professional expertise in the country to sustain the production facility? Is the education system such that professionals will continue to be available?

- What arrangements can be made for parts and maintenance of foreign-bought machinery? Are there local materials which can be substituted for standard, but locally unavailable, materials in routine formulations and in packaging?

- What arrangements exist for stimulating local production? Management contracts? Protective tariffs? Government subsidy?

- How would quality be monitored and maintained? Would an additional independent laboratory be necessary? Would it be necessary to use foreign, possibly costly, laboratories to provide independent quality assessment?

gure III.F.1.

Categories of Pharmaceutical Manufacture

Category	Subdivision	Examples of products
rimary anufacture	• manufacture of organic medicinal substances by chemical synthesis and purification of the end product	chloroquine, paracetamol, isoniazid, metronidazole, piperazine citrate
	• manufacture of medicinal and other substances by fermentation followed by extraction and purification of the product	streptomycin, benzyl-penicillin, vitamin B12, alcohol, acetic acid
	• extraction and purification of naturally occurring substances of vegetable or animal origin	caffeine, digoxin, quinine, insulin
	• extraction of naturally occurring materials without isolation of the active material	tincture of belladonna, liquid extract of licorice, olive oil, eucalyptus oil
	• purification of naturally occurring mineral substances	kaolin, liquid paraffin
	• manufacture of inorganic materials, for example, by precipitation reactions	magnesium carbonate, aluminum hydroxide
	• manufacture of multipurpose materials by a variety of routes	glycerin, sugar, starch
econdary anufacture	• liquids not required to be sterile, for oral use	piperazine citrate elixir, suspension of co-trimoxazole
	• liquids not required to be sterile, for external use	benzyl benzoate application, methyl salicylate liniment, calamine lotion
	• powders for external application	antifungal dusting powders, plain dusting powders
	• ointments and creams for topical use	hydrocortisone ointment, or cream, sulphadiazine ointment
	• tablets	propranolol, sulphadimidine, hydrochlorthiazide
	• capsules	ampicillin, chlordiazepoxide
	• liquids for injection (sterile)	ampules of hydroxocobalamin, 500 ml containers of intravenous fluids
	• preparations for external use that are required to be sterile	eye ointments, eye drops, eye lotions
	• vials of sterile powder for preparation of liquid injections	fortified injection of procaine penicillin, injection of streptomycin
acking	• bulk packs for dispensing	tablets, capsules in e.g., 100's, 500's or 1000's, liquids in 2 liter packs
	• course-of-therapy packaging and other small packs for direct use by the patient	tablets in 50's, 100's, 28's, etc.
	• packs designed to ensure patient compliance	calendar packs, e.g., oral contraceptives, metered aerosols

Secondary manufacture involves the processing of active medicinal substances, usually in admixture with non-active materials (which must also be of pharmaceutical grade) to produce pharmaceutical dosage forms.

The manufacture of any product usually involves a sequence of unit processes which, according to the nature of the product, may include some of the following: milling of coarse materials, sieving of powders, mixing of powders, granulation, subdivision of powders (as in filling of capsules or antibiotics into vials), tablet compression, drying, distillation, filtration, homogenization, sterilization, etc. The conditions for each unit process in the total manufacturing process must be clearly defined and rigidly observed to ensure the reproducibility required for a dependably uniform product. It has inadvisedly been said that ". . . secondary manufacture is not true pharmaceutical manufacture, but merely the processing of materials into pharmaceutical forms". This is a potentially dangerous view since it may easily lead to the belief that quality control in secondary manufacture is of lesser importance than in the so-called "true" pharmaceutical manufacture (i.e., primary manufacture).

Packaging necessarily entails the protection of the product against contamination, deterioration, and physical damage. It may also provide protection against pilferage and be designed to facilitate accurate patient compliance with required dosage schedules. Examples of aids to compliance with dosage schedules are calendar packs of tablets or capsules and metered doses of aerosols for inhalation.

2. TO MANUFACTURE OR NOT TO MANUFACTURE

The local manufacture of essential drugs is being actively promoted by the WHO, UNIDO, and other international assistance agencies as a means of reducing national drug bills and thus releasing funds for other activities of the health services. It appears to be an attractive proposition since, in addition to savings in costs for the health services, many other potential benefits may be cited:

- Greater control over the quality of medicines may be exercised;
- Medicines can reach the consumer in a shorter time after manufacture and thus be less liable to deterioration;
- Continuity of supplies may be improved;
- Less of the nation's foreign exchange is required for drug imports;
- Employment is created in the pharmaceutical industry itself and perhaps also in ancillary industries such as manufacture of packaging materials and printing;
- The introduction of industry necessitates the development of expertise which may be of general benefit to the country (e.g., the development of skills in engineering and instrument maintenance).

However, these are potential and not guaranteed benefits. Without a proper quality control system operated by competent and conscientious personnel, the quality of drugs produced will certainly be inferior to those imported from reliable sources. If dosage forms are not properly formulated, they may be initially ineffective and/or they may deteriorate rapidly. If the procurement and stock control of raw materials and packaging materials is not properly managed, continuity of supplies of the finished products cannot be assured. And if the whole operation is not competently managed, the costs may be higher than those of imported drugs.

Factors to be considered by a developing country that is proposing to introduce some form of pharmaceutical manufacture include:

- The size of the potential market;
- The varying complexity of different types of manufacture;
- How to build up the nucleus of professional and technical personnel to manage the operation;
- How to acquire the technology; and
- Accessibility of raw materials and packaging materials.

The following discussion considers some of these factors separately for the different facets of pharmaceutical manufacture. Transfer of technology and training are discussed further in section 3.b. of this chapter. Appendix III.F.1. lists international agencies and other organizations that can be contacted for technical assistance in local production.

a. Primary Manufacture

Organic Medicinal Substances -- Considering first the synthesis of medical substances (fine chemicals), the starting materials of the fine chemical industry are the end products of the heavy chemical industry, which includes the petrochemical industry. The desirability of ease of access to such starting materials is self-evident. Many of these materials are flammable, toxic, caustic, or otherwise hazardous and, if imported, are liable to generate problems in transportation and therefore in costs. A few examples of materials used in fine chemical manufacture are:

- concentrated acids
- strong alkali solutions
- acetone
- benzene
- chlorinated hydrocarbons
- β picoline
- phosgene
- chlorine

Synthetic Manufacture -- Synthetic routes to a medicinal substance may necessitate the manufacture of several intermediate substances. A new primary manufacturing venture may start its synthesis operations by purchasing intermediates and carrying out only the later or final processes of the synthetic route. As expertise is acquired, then synthesis of the intermediates from more basic materials may be undertaken. It is often desirable to aim ultimately for the complete synthesis, since the cost of intermediates may be kept artificially high by suppliers who are themselves manufacturers of the final medicinal substance.

Antibiotics by fermentation -- Another major form of primary manufacture is the production of antibiotics through fermentation followed by extraction and isolation of the pure product. In addition to problems faced in synthetic manufacture, fermentation has its own specific additional problems. While raw materials for the fermentation process may be available locally, the extraction and purification process requires the purchase of materials such as solvents and ion exchange resins in large quantities. A more serious problem, however, is the control of the fermentation process. This requires a high degree of automation and/or supervision by well experienced professional personnel. High yields can only be attained through use of a suitable culture which would be very expensive to purchase or develop. If high yields cannot be attained, then the process cannot be commercially viable. Thus, the manufacture of antibiotics by fermentation seems worthy of consideration only by those countries having a potential market large enough to justify the heavy capital expenditure on plant and technology and the continuing costs of professional supervision.

Extraction and Purification of Naturally Occurring Substances -- Naturally occurring substances such as alkaloids might be extracted from vegetable sources and prepared either in crude or highly purified form according to the technology available. The former would be of value for their export potential, whereas the latter could also be used in local secondary manufacture. While the technology would not present any great problems, such an operation seems most likely to succeed as a minor activity attached to a secondary manufacturing plant already having the necessary quality control facilities.

Vegetable Drugs -- When potentially useful vegetable drugs are available locally, then as the required technology is relatively simple, the production of tinctures and extracts would be worthy of consideration. Such a possibility is economically more attractive if alcohol of local manufacture is available for the extraction. Compound tincture of cardamom, tincture of ginger, and liquid extract of licorice are examples of preparations made from local materials in one developing country in South Asia.

Mineral Substances -- When naturally occurring mineral substances such as chalk, kaolin, or talc are found locally, then their processing to yield a pharmaceutical grade product might be worthwhile. Such production is likely to be economically viable only with a substantial market such as an export market.

Inorganic Substances -- Inorganic substances used in medicine are mainly low cost materials. While the technology needed for their production is generally straightforward, because of their low cost, manufacture could be worthwhile only if starting materials were readily available and the demand for the product sufficiently great. Certain common antacids are examples of such products.

Multipurpose Materials -- There are many materials that have uses in pharmaceutical as well as other industries, such as in food, cosmetics, and miscellaneous industries. Examples are sugar, starches, fixed oils, volatile oils, glycerin, alcohol, and glucose. For pharmaceutical use, special grades are defined in pharmacopoeial monographs so as to ensure, for example, that the material is non-toxic, non-irritant, compatible in pharmaceutical formulations, and stable during the shelf life of such preparations. If such multipurpose materials are already being manufactured in a country, then it is

necessary to establish whether a grade suitable for pharmaceutical use is, or can be, produced regularly.

b. Secondary Manufacture

This is a field in which developing countries, including some of the smaller countries, have greater possibilities of success. Input materials are normally more convenient and, with some exceptions, less hazardous to handle than those of primary manufacture. The skills and knowledge necessary to manufacture "simple" pharmaceutical products should be attainable by most countries over a period of a few years. Progress towards more advanced pharmaceutical processing may be made as the necessary knowledge, skills, and management capability in production and quality control are attained. Phased development should be accepted as an essential feature in any project to set up production facilities. To attempt too much at an early stage would be to invite disaster, leading to a loss of confidence on the part of prescribers and consumers that would be extremely difficult to restore. Indeed, establishing confidence in the first place is one of the "hurdles" that a new pharmaceutical enterprise has to overcome.

A typical phasing of development might be:

Phase 1

(1) Manufacture of liquids that are not required to be sterile. Examples of such preparations that are widely used in primary health care include elixir of piperazine citrate, application of benzyl benzoate, and mixture of kaolin.

(2) Manufacture of simple tablets and capsules. These would be capsules and tablets that contain a high dose of active ingredient and thus do not present any serious problems in blending of the mix of active ingredient with excipients. They do not include sustained release formulations and other products with high potential for bioavailability problems. Examples include phthalylsulphatiazole 500 mg., paracetamol 500 mg., chloroquine phosphate 250 mg., tetracycline 250 mg., and chloramphenicol 250 mg.

(3) Preparation of topical ointments and creams such as sulphadiazine ointment 5%.

(4) Mixing and packaging of oral rehydration salts in sachets of 27.5 g.

Phase 2 -- Manufacture of products required to be sterile, for which the sterilization process is applied to the product when filled into its final container, e.g., water for injection in 5 ml. or 10 ml. ampules, dextrose 25% in 20 ml. ampules, normal saline intravenous fluid in 500 ml. bottles, and certain eye drops.

Phase 3 -- Manufacture of products required to be sterile which are prepared using aseptic techniques and are not subjected to a terminal sterilization. This includes antibiotics in vials such as streptomycin sulphate and fortified injection of procaine penicillin. Oral contraceptive tablets which contain minute doses of active ingredient and require

single tablet assays might also be included at a late stage of development when quality control facilities are adequately advanced.

The above scheme is offered as a guide only. It is neither complete, nor intended as an inflexible framework for development. Thus, while the manufacture of intravenous fluids calls for special care in the standardization of the manufacturing procedures and quality control routines, it might be considered appropriate to introduce such manufacture at an early stage, provided that adequate safeguards could be incorporated through intensive training and concentration of effort in this narrow field. Decisions on the phasing of any program should be taken in the light of local circumstances and the recommendations of a competent feasibility study team.

c. Packaging

In any project for the establishment of secondary manufacture, the packaging process and its cost is necessarily taken into consideration. It is also possible to establish a purely packaging operation based on imported finished products. This might itself be the final objective or it may be a first step towards the start of secondary manufacture.

The advantages of local packaging are as follows:

- Regardless of their manufacturer and source, products could be presented to the pharmacist or dispenser, prescriber, and consumer in a standard pack form with standard (generic title) labelling including local language(s) and possibly pictorial dosage instructions.

- The distribution chain might be organized in such a way that there is rapid turnover of stocks, thus permitting the use of more economical packaging materials which do not offer the same protection to the product.

- Pack sizes can be varied at will to meet varying demands, e.g., course-of-therapy dispensing packs.

- It provides employment.

- It might create a need for the establishment or development of local facilities to manufacture the packaging materials.

Possible disadvantages are as follows:

- Imported products are already packed when they are received; thus, in effect, the program is paying twice for packaging. Some items such as tablets (the major dosage form) must be supplied in containers of a maximum size (e.g., not greater than 5000 tablets) so as to protect them against breakage due to mechanical shock in transit. Thus, there is already a significant packaging component in the cost of the imported bulk.

- Certain packaging materials such as bottles or rigid plastic containers for tablets, creams, liquids, etc. are necessarily bulky and so may incur shipping charges as high as they would if they were filled.

3. PREREQUISITES AND RESOURCES FOR PHARMACEUTICAL PRODUCTION

The need for medicines to be reliable and to do the job for which they are administered is self-evident. To achieve this level of reliability it is imperative that pharmaceutical manufacture be carried out under appropriate conditions with a high level of professional supervision and management. Only in this way can it be expected that the consumers will be satisfied and the manufacturing unit will be financially viable. Therefore, many factors must be carefully evaluated before embarking on a manufacturing program.

a. A Market

Before considering resources needed for manufacture, it is necessary to establish that there will be a continuing demand for the products. When a manufacturing enterprise is set up specifically to supply public health services, then its market appears reasonably secure, provided government funding is dependable. If, however, it is intended to offer products for sale in the private sector in a free market society, then keen competition must be anticipated and public preference for imported products overcome.

b. Manpower, Training, and Transfer of Technology

A nucleus of persons having the basic technical/professional qualifications is necessary to provide competent management. Also, a population must be available from which can be drawn persons having the potential to become the skilled technicians and semi-skilled operatives who will do the routine work of manufacture, filling and packing, etc. In essence, there must be an "educational pyramid" with a sufficiently broad base to assure an adequate supply of trained individuals.

For secondary manufacture and packaging, the following professional and technical skills and knowledge are required:

- Pharmaceutical Sciences -- for manufacture and product development; for quality control including chemical, physical, microbiological, and possibly pharmacological control.
- Engineering Sciences -- for maintenance and repair of machinery, plant and service installations such as electricity, water, steam, and air conditioning; for routine maintenance and minor repairs to instrumentation in the plant and in the laboratory.
- Financial Management -- to control/guide in matters pertaining to costs.

For primary manufacture the following professional expertise would be needed in addition, depending on the exact nature of the manufacturing operations:

- Chemical Engineering -- for design and maintenance of the plants.
- Organic Chemistry -- for manufacture and process development.

- Industrial Fermentation -- for routine control of manufacture and for process development.

Depending on the previous experience of the technical and professional staff recruited, additional training may be required. This will certainly be the case for new graduates. Nationals with appropriate experience in industry overseas might also be recruited.

The transfer to technology must be considered along with staff training. The further training of graduate staff is, in itself, a transfer of technology. However, some processes may have to be purchased. The ideal should be to have a small facility for pharmaceutical development (developing and testing formulations) so that the local production unit can modify formulations for secondary manufacture as may be necessitated by differences in the characteristics of input materials obtained from different sources. The professional and technical staff should be expected to plan and implement training courses for potential skilled and semi-skilled operatives.

c. A Site for the Enterprise

A site must be found having access to the following:

- Water of suitable quality. Depending on the mineral content of the water supply, the cost of treatment to render it suitable for use in the plant boilers and in pharmaceutical manufacture could be high. Hence, it is important to evaluate the water supply before final selection of a site.

- Power Supply to operate the various instruments needed in the manufacturing process, and to light and possibly regulate the temperature of the plant environment.

- Communications for the convenient transportation of raw and packaging input materials and of the finished output products which must be transported to depots en route to the consumers.

- A source of manpower for potential skilled, semi-skilled, and general labor.

- Facilities for the disposal of waste -- This is particularly important in primary manufacture and especially in fermentation processes.

The environment should be conducive to pharmaceutical manufacture, preferably a non-congested area with a clean atmosphere, perhaps in open country or in an area in which only light industries will be permitted.

d. Buildings

Buildings for the manufacturing plant, quality control laboratories, storage of input materials and finished products, quarantine areas, and administrative services are needed. These must be designed with an appreciation of the operations that are to be carried out and the code of good manufacturing practices.

e. Finance

Components of the cost of establishing a pharmaceutical manufacturing enterprise are:

- Site and services.
- Buildings and material facilities for production, quality control, warehousing, maintenance services, administrative services, personnel services, and transport.
- Transfer of technology (staff training and purchase of technical know-how).
- Working capital. This is a very substantial item of which the investment in raw materials is a major component. The cost of raw materials is generally high and when these must be imported, the length of time between purchase and finally receiving payment for them in their processed form will usually be at least eight months.

4. DETERMINING THE VIABILITY OF LOCAL PRODUCTION

Let it be assumed that a government, concerned about the cost of medicines used in its public health services, wishes to investigate the possibility of reducing costs by commencing manufacture of some medicines locally in its own plant. The first step is to assess what is entailed in such a venture, what it is going to cost, and what are the likely benefits. The essential features of such a feasibility study include the following:

(1) A description of the existing pattern of drug consumption and costs.

(2) Identification of drugs that represent major components of the total costs

(3) Selection of drugs for possible inclusion in a local manufacturing program and estimation of quantities required.

(4) Postulation of an annual production program and estimation of the material facilities required for that program.

(5) Estimation of personnel needed for the postulated program and the need for additional training.

(6) Estimation of needed capital investment and running costs.

(7) Estimation of ex-factory cost of the products based on capital investment, cost of labor and services, cost of input materials.

(8) Comparison of ex-factory costs and of their foreign exchange components, with most favorable import costs.

(9) Review of constraints and prospects for success.

(10) Presentation of report and recommendations.

Figure III.F.2.

Estimating Required Resources for a Pharmaceutical Plant

A. EXPECTED PRODUCTION PROGRAM

- Specify products, dose forms, package sizes, and quantities.
- Determine convenient batch sizes.
- Estimate:
  - total ingredient cost,
  - total container cost,
  - total weight and volume of input materials,
  - total weight and volume of output materials.

B. PRODUCTION FACILITIES AND PERSONNEL REQUIREMENTS

- Estimate plant capacity needed for each type of product, based on postulated production program and batch size.
- Plan plant layout and estimate space required for manufacture, packaging, and ancillary activities, based on production processes and expected volume of production.
- Estimate professional and support personnel needed for the program.

C. WAREHOUSING AND TRANSPORTATION FACILITIES AND PERSONNEL REQUIREMENTS

- Estimate space and material handling equipment needed for warehousing, based on annual consumption of raw materials, packaging materials, their weights and volumes, and their expected transit time between receipt and processing.
- Estimate space and facilities required for finished goods until they leave the factory.
- Estimate number and capacity of vehicles needed, based on quantity of goods, distance from port, and distance from the various depots to which finished goods must be delivered.
- Estimate professional and support staff needed.

D. QUALITY CONTROL FACILITIES AND PERSONNEL REQUIREMENTS

- Assess the laboratory equipment and consumable materials needed, based on range of products, expected batches of each product, the specifications for active and inactive ingredients, packaging materials, and the finished products.
- Plan the layout of the laboratory, and estimate the space, fixtures, and furnishings required, based on the equipment and intended operations.
- Estimate the professional and support personnel needed for the program.

E. MANAGEMENT AND ADMINISTRATIVE SERVICES

- Assess personnel requirements for:
  - production planning,
  - procurement,
  - sales/distribution administration,
  - transportation,
  - personnel services,
  - security and cleaning.

- Assess the office and other space needed for these services/activities, their fixtures, and furnishings.

F. UTILITIES (Power, Water, Steam, Air Conditioning, Effluent Disposal, etc.)

- Estimate the water and power needs, etc., based on the planned production activities, power requirements of plant, heating/cooling requirements, clean air control, and general requirements of the administrative services offices.

- Estimate the professional and support personnel needed for maintenance and operation of these main services and to provide maintenance and repair services to the manufacturing plant, laboratory, etc.

G. PERSONNEL, FURTHER TRAINING AND TRANSFER OF TECHNOLOGY

- Considering the already estimated needs for professional personnel, assess the various possibilities of recruiting persons having suitable basic qualifications, and assess the probable needs for additional training and its cost.

- Assess possible costs for transfer of technology by means other than staff training.

H. FINANCE

- Assess initial investment and running costs as a basis for arriving at an estimated ex-factory cost of finished products. Items to be considered are:

  1. Investment in Fixed Assets -- site; buildings; major installations and services (power, water, air conditioning, etc.); manufacturing plant, packaging and warehouse equipment; laboratory equipment; and office fixtures, furnishings, and other equipment.

  2. Initial Investments -- installation and start-up of plant; training; and transfer of technology.

  3. Working Capital -- investment in process materials; and other items.

  4. Running Costs -- power and water; salaries and wages; process materials; stationery and office materials; telephone, telex, postage; taxes and insurance; and transportation.

An approach to the estimation of the required resources and feasibility of an entire project, and the resultant cost of products ex-factory, is summarized in Figure III.F.2. The ex-factory cost is the total cost of producing a product and includes all expenses incurred until its manufacture is complete and it is ready to be shipped from the plant.

The ex-factory cost of an individual product may be estimated quite simply. The components of ex-factory cost are the following:

- cost of input materials (raw materials and packaging materials),
- costs of manpower, both directly and indirectly concerned with the manufacture,
- interest on capital investment (material assets and working capital),
- cost of services such as power, water, communications, insurance, etc.,
- depreciation of plant and equipment.

There are various alternatives for apportioning these costs between the different products. The simple methods shown here and in Figure III.F.3. give estimates very similar to those obtained by a more complex method, and there is no reason to suppose that it is less reliable.

The total ex-factory costs can be very simply estimated thus:

Let, a = annual cost of all input materials,
b = annual total operating cost of factory,
c = ex-factory cost of annual production,

Then, $a + b = c$

On average, the ex-factory cost of any individual product can be estimated as, for example with Product A,

Product A input material cost x c/a = ex-factory Product A cost.

In other words, the product cost of any individual product is taken to be proportional to the input raw material cost. Figure III.F.3. provides some sample calculations.

Country Study III.F.1. describes a feasibility study of alternative systems for repackaging drugs in one Asian Country.

5. IMPLEMENTING A PROGRAM FOR LOCAL PRODUCTION

The experience of countries that have established, or endeavored to establish, pharmaceutical manufacture during the past two to three decades should serve to guide those countries that are now contemplating venturing into pharmaceutical production. It is among the countries with larger populations that most progress has been made in developing pharmaceutical technology

Figure III.F.3.

Estimation of Ex-Factory Cost of Products

The establishment of a pharmaceutical plant having the following production capacity was proposed:

tablets	600 million	sachets (oral rehydration salts, etc.)	6 million
capsules	90 million	ointment, 20 g. tubes	2.25 million
liquids (non-sterile)	257,000 liters	water for injection, 5 ml. ampules	9 million

Costs for MATERIAL FACILITIES (capital investment) were estimated as follows:

land and buildings	U.S.$6,440,000	packaging	60,000
transfer of technology	1,014,000	material handling (warehousing)	452,000
office equipment and furnishings	254,000	quality control	440,000
manufacturing equipment for		engineering services	40,000
tablets	1,838,000	transport	254,000
capsules	292,000		
liquids, non-sterile	278,000	TOTAL COSTS	
ointments, non-sterile	184,000	OF MATERIAL FACILITIES	U.S.$12,936,000
sachets	662,000		
ampules	728,000		

The total cost of INPUT MATERIALS was estimated at U.S.$20,726,000. Since adequate stocks of input materials must be maintained at all times so that the plant can be properly utilized, additional capital is required. This is termed working capital, and, in this instance, was estimated as follows: The time taken between opening a letter of credit for the purchase of materials and their eventual processing is assumed to be, on average, six months. It is also assumed that after processing, a further 2 months will elapse before these goods are sold and payment received. Thus, it was estimated that about 70% of the cost of input materials, or U.S.$14,508,000 was tied up as WORKING CAPITAL. Additionally, working capital equivalent to 25% of annual costs of labor, services, etc. is needed.

Annual OPERATING COSTS were estimated as follows:

depreciation of equipment	U.S.$500,000	offices and telephone	160,000
engineering services and maintenance	420,000	insurance	80,000
power and water	800,000	contingency fund	160,000
laboratories	650,000	SUBTOTAL	U.S.$2,770,000

(not including salaries and wages, or interest on the investment, which vary.)

The foregoing data is used to estimate the ex-factory cost of 100,000 x 1000's sulphadimidine tablets, 500 mg., in three different circumstances:

Plan A: very low salaries and wages totalling U.S.$656,000; finance by an interest free loan (service charge of 0.75%).
Plan B: very low salaries and wages totalling U.S.$656,000; finance by a loan at 12% interest
Plan C: moderately high salaries and wages totalling U.S.$ 2,624,000; loan at 12% interest

	Plan A	Plan B	Plan C
cost of material facilities (from above)	U.S.$12,936,000	$12,936,000	$12,936,000
working capital (for input materials, from above)	14,508,000	14,508,000	14,508,000
working capital (for operating costs)*	909,660	1,731,726	2,238,930
TOTAL CAPITAL	U.S.$28,353,660	$29,175,726	$29,682,930
subtotal annual operating costs	U.S.$ 2,770,000	$ 2,770,000	$ 2,770,000
salaries and wages	656,000	656,000	2,624,000
interest on investment (0.75% or 12%)*	212,652	3,501,088	3,561,952
TOTAL ANNUAL OPERATING COSTS	U.S.$ 3,638,652	$ 6,927,188	$ 8,955,952
total cost of input materials (from above)	U.S.$20,726,000	$20,726,000	$20,726,000
annual operating costs	3,638,652	6,927,088	8,955,952
EX-FACTORY COST OF ANNUAL PRODUCTION	U.S.$24,364,652	$27,653,088	$29,681,952
$\frac{\text{ex-factory cost}}{\text{input cost}} = \frac{\text{ex-factory cost}}{\text{U.S.\$20,726,000 (in Plans A,B,C)}}$ =	1.176	1.334	1.432

Where the cost of input materials for 100,000 x 1000's sulphadimidine tablets, 500 mg., is U.S.$1,505,160, the EX-FACTORY cost is estimated as:

Plan A: U.S.$1,505,160 x 1.176 = 1,769,406, or U.S.$17.69 per 1000 tablets
Plan B: U.S.$1,505,160 x 1.334 = 2,008,218, or U.S.$20.08 per 1000 tablets
Plan C: U.S.$1,505,160 x 1.432 = 2,155,558, or U.S.$21.56 per 1000 tablets

These three estimates of ex-factory cost should be compared with the CIF price available for large scale purchases by an efficient procurement agency (e.g., U.S.$20.90 per 1000 tablets). The foreign exchange component of the manufacturing cost was U.S.$15.06 per 1000 tablets.

*obtained by iterative calculation not shown.

Country Study III.F.1.

Feasibility of Alternative Packaging Systems for a Large-Scale Government Pharmaceutical Supply Service: A Study from Asia

1. PREFACE

Packaging of pharmaceuticals, especially tablets, has reached a sophisticated state which facilitates proper health care by assuring that the correct unit dosage is delivered to the patient rapidly and with the minimum of administrative, production, and personnel errors. This paper outlines the present system of packaging, presents three alternative systems, and proposes the acquisition of a comprehensive packaging system which affords the patient safe delivery of drugs, more suitably dispensed than in the paper envelopes currently used.

2. PRESENT SYSTEM OF PACKAGING

Tablets are currently packed in tins of various shapes and sizes ranging from 4 x 4-1/2 x 4-1/2 inches to large biscuit tins, and in various quantities ranging from 1,000 units to 10,000 units, and 18,000 in one instance. Tablets are dispensed to patients in hospitals and clinics in paper envelopes. Advantages of the present system are primarily economical in that the large containers substantially reduce packaging and handling costs compared with standard packaging by commercial firms. Disadvantages of the present system include the following:

a. Dangers of labeling -- Since only one external label is used for a large container, the risk of not knowing the identity is high if the label drops off, even though one additional label is packed inside the container. When the outer label is lost, the seal must be broken to determine the drug identity and this prematurely exposes the drugs to the ravages of the climate.

b. Risk in dispensing -- Since tins of 7000 or more tablets are delivered to hospital dispensaries, they must be subdivided in various proportions depending upon the out-patient demand. Heavy utilization of tins in the hospital dispensaries increases the chance that external labels and the inside label will be lost, thereby creating severe risk of mix-up of tablets at the dispensary.

c. Poor stability of the tablets in these containers when opened -- Tablets are dried compact unit dosages and when exposed to high temperature and humidity, the tablets tend to absorb moisture and disintegrate. Furthermore, certain active ingredients are prone to degrade on exposure to high moisture content.

d. Fragmentation of tablets during handling and transport -- Since the tablets are packed in multiples of 7000 per tin, the compression of tablet-on-tablet at the bottom is relatively high. This is further accentuated when the tablets are subjected to standard transport and handling conditions.

e. Inconvenience in dispensing -- The dosage of tablets to the patients is usually in multiples of 21, 42, etc. -- completely different from the present mode of packaging 7000 per tin. This means the dispensers will have to spend time counting tablets from tins and packing them in paper envelopes before they write the instructions on the envelope and finally dispense them to the out-patient. Dispensing of pre-packed tablets also will reduce the workload in the accounting of medicine being supplied to patients.

f. Poor Preservation of tablet activity -- The paper envelope is not a suitable container for all types of tablets as they are not air tight or water proof; the patient may not be afforded the maximum therapeutic efficacy that is so desired and built into the tablets.

3. ALTERNATIVE METHODS OF PACKAGING

The accompanying table compares four packaging alternatives, the present method of distributing drugs in tins of various sizes (Alternative A), mechanized sachet packaging at the central government medical stores (Alternative B), blister packaging at the central government medical stores (Alternative C), and re-packaging in plastic bags at the 13 regional medical stores around the country (Alternative D).

Sachet packaging -- Mass packaging in plastic bags is generally used for dosage forms of large diameters, items such as condoms, or granular products such as soap powders or effervescent fruit juices. Sachets are usually filled by weight. If small potent drugs are packed in sachets the number variation per sachet is likely to be larger, and the end consumer is inadvertantly allowed more or less than the actual stated number of the tablets described. There are sachet machines which can deliver a very precise number of tablets per sachet, but the requisite intricacy and the electronic incumberances would entail a very high initial capital outlay, thereby defeating the purpose of packaging economically. For example, a sachet packaging machine that can deliver a statistically precise number of tablets per sachet at the slowest production run of forty sachets per minute would require the assistance of an electronic counting machine, calibrated indirectly by weighing, at a cost of U.S.$4,000.

Country Study III.F.1. continued

COMPARISON OF PACKAGING ALTERNATIVES

(Costs based gn 3,000,000 tablets per day in sizes A (3.2 millimeter diameter), B (11.1 mm.), and C (12.7 mm.) in packs of 21 tablets, during 6 hours per day of actual production time.)

	Present method in tins of various sizes A	Sachet Packaging B	Blister Packaging C	Re-packaging at 13 regional centers D
CHARACTERISTICS OF THE SYSTEM				
1. Danger of tablet breakage during packing and transport	Yes	Yes	No	Yes
2. Absolute number of tablets per package	No (10% error)	No (5% error)	Yes (no seal, no tablet mechanism)	No (count by weighing)
3. Danger of tablet mix-up during packing.	Yes	Yes	No (machine stops when wrong size tablet enters)	Yes
4. Danger of tablet mix-up during dispensing	Yes (when tin opens)	Yes (when sachet is open)	No	Yes (if label drops off)
5. Absolute identity of tablets in pack	No (if label drops off)	No (if sachets are broken)	Yes	No (if label drops off)
STAFF REQUIRED				
6. Operating Personnel	1 Lab. Assist, 1 Attendant, + 12 Dispensers, (part time)	10 Lab. Assts., 30 Attendants	3 Lab.Assts., 9 Attendants	1 Dispenser x 13 = 13 Dispensers 2 Attendants x 13 = 26 Attendants
SPACE REQUIRED				
7. Machine space required	884 sq.ft.	810 sq.ft.	337.5 sq.ft.	8 sq.ft./center = 104 sq.ft.
8. Packing/storage space required	332 sq.ft.	162 sq.ft.	162 sq.ft.	40 sq.ft./center = 520 sq.ft.
9. Total operating space (7. + 8. above)	1,216 sq.ft./day, (height 5 ft.)	972 sq.ft./day (height 10 ft.)	499.5 sq.ft./day (height 10 ft.)	624 sq.ft./day (height 12 ft.)
10. Storage space for packed products (3 million tablets)	6,696 cu.ft./day (height 5 ft.)	45,198 cu.ft/day (height 12 ft.)	36,158.4 cu.ft/day (height 12 ft.)	600 sq.ft. for 1 wk. storage at dispensary (height 12 ft.) Total 7,210 cu.ft./ week for each center
11. Storage occupancy[a] at dispensing bench	3 sq.ft.	18 sq.ft.	16.7 sq.ft.	22 sq.ft.
ESTIMATED COSTS				
12. Investment (machinery)	- - -	U.S.$376,202 10 machines	U.S.$119,188 3 machines	U.S.$46,800 13 machines
13. Packing cost per 21 tablets — TABLET A	0.023¢	0.124¢	0.116¢	0.12¢
TABLET B	0.087¢	0.264¢	0.38¢	0.2¢
TABLET C	0.097¢	0.264¢	0.38¢	0.28¢
14. Cost of packaging material for 3 million tab/day (assume Tablet C)	$81.60 for tins average out on 0.097¢/ 21 tablets	$377.20 for sachets at 0.264¢ each for 21 tabs	$542.80 for blister at 0.38¢ for 21 tabs	$22/day of 230,769 tablets at each of 13 centers. Total = $285.60 in all centers plus Col. A.
15. Cost of outer cartons[b]	- - -	143 x $2 = $286	143 x $1.20 = $171.60	Propose using old IV boxes, free of cost
16. Total running cost in packaging 3,000,000 tab/day (14. + 15.)	$81.60	$663.20	$714.40	$22/day for each center = $285.60
17. Cost estimate for staff (see 6.) per year	$1,992	$33,360	$10,008	$3,336 x 13 = $ 43,368
18. Total Annual Operating Cost[c]	$21,603 (excluding part-time Disp.)	$192,513	$181,478	$131,550
19. Capital Cost on Machinery and Operating Cost for First Year (Items 12. + 18.)	$21,603	$568,715	$330,666	$178,350

[a] Storage space at dispensing bench based on 75 prescriptions per hour at average of 3 types of tablets per prescription.

[b] Based on 3 million tablets per day in containers of 1000 sachets or blisters each (142.8 cartons for 3 million tablets)

[c] Total annual cost for packing 3 million tablets per day, 240 days per year, based on full 8 hour working day. (Item 16 x 240 + Item 17; Item 12, cost of machinery, is excluded).

Country Study III.F.1. continued

During transport and storage, some breakages will be encountered as the tablets are not properly oriented in the pack, especially with the larger tablets. The end users face the problems of deterioration and contamination as soon as they use one of the 21 tablets in the sachets by breaking open the sachet.

But machinery is the biggest problem. No doubt there are sachet machines with an output of 100, 200, or even 400 sachets per minute, but the problem is the tablet feeding. A double electronic weigher can cope with about 40 sachets/minute of 21 per sachet. The total machinery investment for the sachet machine in comparison to the blister packaging one would be four times higher. Therefore, it is not advisable to propose that tablets be packed by sachet methods.

Blister packaging -- In blister packaging the individual tablets are encased in the plastic mold and are heat sealed by rolling a preprinted aluminum foil over the mold. In this case the use of the electronic weighing machine is obviated as the tablets are guided down the hopper on to the mold and sealed in a simultaneous on-line process. The laminate is in continuous strips and can be segregated into aggregate multiples of 21, 42, 96, or more tablets per pack.

It can be seen that for blister packing, the initial equipment and operating costs are half of that for sachet packing. The sachets will occupy double the storage area in the laboratory compared to the blister packaging. Finally ten operators will be required to man the sachet machines against three for the blister packaging machinery.

To package 3 million tablets of various sizes in 6 hours by the blister packaging method, 3 machines will be required at the price of U.S.$119,188 while the space occupied by the machines is 25 sq.m. compared to the use of ten sachet packaging machines at the cost of U.S.$376,202 and occupying an area of 90 sq.m.

Packaging at the regional level -- An alternative to the major capital expenditures for sachet or blister packaging is the use of an electric tablet counting machine with a heat sealer at each of 13 regional stores.

The cheapest tablet counting machine to count to 100 tablets per pack costs about U.S.$2,800. This machine can count any number of tablets per pack on a see-saw channel. That is, a counted number of tablets will be continuously delivered by the machine and see-saw channelled out of both sides of the machine -- something like the coin-counting machine at the bank. The biggest problem with this machine is the speed of the operator. The slow operator will give a low output while a fast worker will give between 5 to 6 packs per minute of operation subject to the maximum of 100 tablets.

The packaging material would be PVC (poly-vinyl-chloride) bags sealed with a heat-sealing machine. The use of PVC in packing medical products like tablets has led to some adverse reports on the keeping qualities of the tablets.

The capital costs would be U.S.$2,800 for each electric tablet counting machine and $800 for each PVC sealing machine for a total of $3,600 per center. From the accompanying table it may be noted that while the initial outlay is a little lower, the staff implications are much larger, and the potential for dispensing and packing errors still exists.

4. CONCLUSION AND PROPOSALS

Based on the foregoing paragraphs and the accompanying table it is recommended that blister packaging of tablets woudd serve the greater interest of and render better health care to the public; the tablets are individually sealed and the patients are afforded the maximum security, safety, and efficacy of the drug when they are supplied through the government hospital dispensaries. However, there is a constraint in that larger storage areas are required for tablets packed in blisters. Assuming that the packaging machineries will take 18 months to be functional, then storage constraints at the Central Store level may not be so severe if the Regional Store is operative a short while after. In addition, constraints placed by storage requirements in the dispensary areas might present problems if new pharmacy and dispensary building programmes are curtailed.

If blister packing is to be adopted, the following would be required:

1. U.S.$119,188 for machinery
2. 3 Laboratory Assistants
3. 9 Laboratory Attendants

(1975)

Adapted from a report prepared in 1975 by the Pharmaceutical Production Unit of the Ministry of Health Pharmacy Division in one of the advanced developing countries of Asia. Subsequent to the report, the government successfully introduced a system of blister packaging for common tablet forms. Prices converted to U.S. dollars.

in the private or public sectors. For example, India and Turkey are virtually self sufficient as regards secondary manufacture and have established some primary manufacture. Countries that produce a high proportion of their consumption include Burma, Egypt, Indonesia, and Thailand. Local production is believed to account for more than 20% of consumption in Iraq and Jordan, and this may be increasing.

But success cannot be measured in terms of volume of production relative to demand alone; quality of the products must also be considered. (Moreover, it should be recognized that "demand" is not synonymous with "need".) It is

Country Study III.F.2.

Pharmaceutical Production in Selected Countries

Southern Asia -- A company established about 25 years ago as an overseas subsidiary, but since nationalized and operating as a government factory. It has a total staff of over 2000 and produces a wide range of medicines. Much of its equipment is antiquated due to lack of foreign exchange to replace it. Nevertheless, this factory has an impressive output due to the perseverance of its engineering and pharmaceutical staff working under very difficult conditions.

Western Asia -- A production unit established in the early 1970's to provide a range of about 50 drugs for use in government hospitals, and having a total staff of perhaps 30 or 40. Despite lack of financial constraints, there was inadequate know-how, no in-house laboratory control, and lack of appreciation of the code of good manufacturing practices. It is understood that the situation has improved much in recent years.

Southern Asia -- A production unit set up in the early 1970's to provide a small range of drugs for use in government health establishments, and having a total staff of perhaps 20 to 30 persons. The unit had come into being (as part of a government department) several years before any serious feasibility study was undertaken. Despite the conscientious efforts of its management, this small unit continued to make an almost negligible contribution to the nation's needs due to problems beyond the control of management. These difficulties included lack of raw materials due to insufficient allocation of foreign exchange, and lack of continuity of professional/technical middle management due to poor remuneration offered within the rigid limits imposed by a government department's regulations. An eventual feasibility study revealed that the scale of operations originally envisaged was hopelessly inadequate. The constraints imposed by the unit's constitution as part of a government department were brought to light, thus opening the way for a reappraisal of the whole venture.

Eastern Mediterranean -- A company set up as a public enterprise in the 1960's and now employing about 2000 persons. This company appears to have a competent quality control and development department. It supplies medicines to both private and public sectors. Although the country has had considerable economic difficulties, the contribution that a healthy pharmaceutical industry can make is recognized by the government and so the company does not face undue difficulties in obtaining the foreign exchange needed for maintaining and upgrading its manufacturing and control facilities.

Eastern Mediterranean -- A company set up in the early 1970's for the manufacture of antibiotics by fermentation. It is producing tetracycline at a cost greater than current international prices. However, this industry is protected, as imports of tetracycline are prohibited. From the national economy point of view this project is a success due to the saving of foreign exchange. The country has developed substantial expertise and further fermentation projects are under consideration.

Europe -- A unit established to repack pharmaceutical products purchased in bulk for use in hospital services. Tablets and capsules available from manufacturers were generally packed in quantities of 500 or more and not ideal for the needs of the hospital services. The unit repacks a range of about 80 tablets/capsules, generally in 50's. They are repacked in "Securitainers" (polypropylene cylindrical containers having a tamperproof cap). Packing is standardized on only three sizes, 26 x 52 mm., 35 x 52 mm., and 35 x 84 mm. The unit employs 3 part-time workers and is supervised by one pharmacy technician. It has an output of about 500,000 packs per year. Container costs range from U.S. $0.05 to $0.10 each. Overall costs including labor, container, labels, boxes for packing, and depreciation are estimated at about $0.13 per pack. However, quality control services of the hospital service laboratory are not charged. Labor costs are high and amount to about $0.04 per container.

apparent that there are great differences between manufacturers in their understanding and application of the code of good manufacturing practices. Some examples of the varying standards of achievement are given in Country Study III.F.2. and a detailed study is given in Country Study III.F.3.

Before a country embarks on a production program, it must first establish that the quantitative need is sufficient to justify local production and that circumstances are such that local production can be economically viable. The major steps in this evaluation are as follows:

(1) A preliminary assessment carried out by a pharmacist having experience in production and quality control would quickly establish whether the potential scale of manufacture was sufficient to justify a more detailed and considerably more expensive study.

(2) If the more detailed study is found to be justifiable, then a feasibility study team should be appointed to conduct an analysis such as the one suggested earlier. The team might include persons qualified and experienced in the following fields:

- Medicine or pharmacy -- To study the prevalent disease patterns and assess the true needs for drugs and prepare a quantitative list of major drugs that might be considered for manufacture.

- Pharmaceutical manufacture and quality control -- To assess which of the drugs listed might be manufactured, and the equipment and personnel needed for manufacture, quality control, and all supporting services in a manufacturing unit.

- Engineering/construction -- To assess costs of providing the land, buildings, and services.

- Economics -- To assess the economic viability of the proposal.

If the team's conclusion is that local production is feasible, then it should indicate in its report the possible routes to implementation.

(3) The next logical step is to establish the means of transfer of technology The possibilities include:

(a) manufacture of products under license,

(b) joint ventures, between the government of a local company and the overseas company,

(c) management contracts whereby an overseas company agrees to provide the technical know-how and management skills,

(d) development of skills through overseas training.

"Guidelines for the acquisition of foreign technology in developing countries" (UNIDO, 1973) is a useful reference. The acquisition of know-how from the more advanced developing countries is worthy of consideration; some of these countries have well established pharmaceutical industries for their

Country Study III.F.3.

Government Production in Southeast Asia

In one Southeast Asian country, pharmaceutical production has had a long history. Prior to 1964, supply and production were carried out in 18 different facilities, from old garages to rented warehouses; in 1964 new facilities were opened to replace all 18. The new Production Unit was equipped with modern manufacturing machinery for injectables, tablets, and galenicals. Since 1964 almost U.S.$1.5 million has been invested in additional equipment. These facilities, coupled with highly trained personnel, good management procedures, and a continuing government commitment, have contributed to successful pharmaceutical production.

1. Products and Capacity -- The Unit operates near capacity on all lines and frequently runs overtime and on holidays. Its products fall into the following categories:

   a. Injectables -- 67 different single-dose ampules, multidose vials, and 1/2-liter I.V. bottles.
   b. Tablets -- 43 types produced, accounting for 80% of the government's tablet requirements. Tablets requiring critical quality control are avoided (e.g., digoxin and most antibiotics), as are low-volume items.
   c. Galenicals -- 103 antiseptics, syrups, tinctures, ointments, etc.

   During the 14 years the Production Unit has existed, the numbers of ampules and tablets produced have quadrupled, the production of intravenous fluids has increased 40-fold, and the quantity of galenicals produced has more than tripled.

2. Local Formulations -- Several of the products produced are based on local formulations developed to suit local needs or to utilize local products. For example, several of the injections use locally produced coconut oil as a base. A locally prepared sulpha injection for treating leprosy is not available elsewhere and is occasionally requested abroad.

3. Production Costs -- Although production costs are not routinely calculated in the manner of standard industrial practice, the head of the Unit recently prepared a cost comparison which provides a fairly complete picture of the actual costs. For the same quantity of the same items, commercial list prices are about 8 times higher than government production costs. Assuming that these goods could be purchased by tender for 50% of the commercial price, the net savings attributable to government production is about 75% of the estimated tender cost.

   This substantial savings over the commercial cost is due to the absence of land taxes, low domestic wages, the absence of import taxes on raw materials (which reach 25% on imported preparations), greatly simplified packaging, packaging in huge bulk (up to 18,000 tablets per tin), and the absence of payments for research, marketing, and return to investors.

4. Staffing -- The plant is headed by a well-trained experienced pharmacist, and each of the production divisions is headed by pharmacists specialized in industrial pharmacy. The plant operates its own 3-year training course for pharmaceutical production laboratory assistants, which includes basic pharmaceutical sciences, physical pharmacy, chemical pharmacy, biological pharmacy, pharmaceutical manufacturing technology, and practical experience in each of the three production units and the analytical control laboratory.

5. Efficiency -- The low production costs are one measure of the production efficiency of the plant. Another indication is that the yield on raw materials is over 95%. Several factors appear to account for the plant's efficiency:

   a. Labor practices are similar to the commercial sector with regard to holidays and working hours, unlike government production plants in some countries.
   b. At the level of unskilled laborers, management has a free hand to recruit and sack. There is no job security law which makes the sacking of an ineffective laborer difficult.
   c. The staff at the civil service level is generally well qualified. On-the-job training for the supervisory personnel is a rigorous three-year program.
   d. Although the plant does not have an industrial engineer, the present staff has been exposed to various industrial management techniques for improving efficiency.
   e. The present physical plant is relatively well-designed and well-equipped for modern production needs.

6. Quality Control -- The production complex maintains its own analytical control laboratory which is administratively independent from the Production Unit. It reports only to the director of the complex. The administrative independence of the laboratory is intended to assure that the laboratory has quality control as its only incentive and that consideration of production efficiency and loss of materials does not influence the interpretation of the QC reports. The production facility has had no instances of serious adverse effects attributable to substandard quality of its products (1978).

home markets but, not being major exporters, do not fear that providing assistance will also generate competition.

Constraints and Prospects for Success

The foregoing examples show what the project can hope to achieve. They do not give any indication as to whether it will work in practice. For success, a prime requirement is an enthusiastic and competent managerial and technical staff. Conditions of employment must be such that staff remain enthusiastic and are happy to remain with the organization, thus providing the continuity of upper and middle management that is essential for the smooth running of operations. It follows that there must be a realistic salary structure, so the organization must be constituted in such a way that realistic salaries can be paid. It is an unfortunate fact that units set up as government departments often fail to meet these requirements through the rigidity of salary scales.

The importance of strong quality control management cannot be overemphasized. Without this the enterprise will rapidly be discredited and its errors exaggerated.

In conclusion, success can be achieved, but only through very careful planning and execution of the project.

SUMMARY

Pharmaceutical manufacture falls into three categories:

(1) Primary production of medicinal substance and ancillary substances,
(2) Secondary production of pharmaceutical dosage forms,
(3) Packaging from bulk sources into dosage forms to protect against deterioration and possibly pilferage, and to encourage patient compliance with dosage requirements.

Secondary manufacture and subsequent packaging of products seems to be the most likely basis for a successful project in most countries.

Potential benefits of local production include:

- Savings on overall cost of drugs to national health services,
- Savings on foreign exchange to the nation,
- Quality assurance may be facilitated,
- Continuity of supplies may be facilitated,
- Employment is created in the pharmaceutical manufacturing enterprise itself as well as in ancillary industries.

The above are potential NOT guaranteed benefits.

Quality in local production must be assured in any local production enterprise to: (1) protect the consumer and (2) protect the reputation of the manufacturer. If the reputation is harmed, then the success of the project is endangered. Quality assurance may be facilitated by:

- Avoiding overambitious production projects at too early a stage,
- Realistic phasing of the development of the production program,
- Institution of a strong quality control system.

Prerequisites for success include:

- A sufficiently large market/need for the products,
- Personnel with skills in pharmaceutical production and quality control, engineering, accounting, and general management.

Elements of a study of the feasibility of local pharmaceutical production include:

(1) Assessment of which drugs are needed in sufficient quantity to warrant consideration of local manufacture,
(2) Postulation of an annual production program,
(3) Estimation of material facilities needed for manufacture, quality control, warehousing, engineering maintenance, and general services,
(4) Estimation of personnel required for production and quality control, as well as for general administration, office services, security, housekeeping, and personnel services,
(5) Estimation of ex-factory costs of finished products.

Success is most likely with:

- An enthusiastic and competent technical, professional, and management organization,
- A realistic salary structure to sustain enthusiasm and competence,
- A strong quality control system/management to safeguard the reputation of the manufacturing venture.

CHAPTER III.F. REFERENCES*

Cilingiroglu, A.: Transfer of Technology for Pharmaceutical Chemicals. Paris: Organization for Economic Cooperation and Development, 1975.

Lall, S.: Price Competition and the International Pharmaceutical Industry. Oxford Bulletin of Economics and Statistics 40: 9-23, 1978.

Lall, S.: The Growth of the Pharmaceutical Industry in Developing Countries: Problems and Prospects. New York: United Nations, 1978.

Dunnill, P.: The Provision of Drugs by Appropriate Technology. Appropriate Technology 4 (2): 16-17, 1977.

Institute of Medicine: Pharmaceuticals for Developing Countries. Conference Proceedings. Washington, D.C.: National Academy of Sciences, 1979.

UNIDO: Guidelines for the Acquisition of Foreign Technology in Developing Countries. New York: United Nations Industrial Development Organization, 1973.

UNIDO: Acquisition of Technology from Multinational Corporations by Developing Countries. New York: United Nations Industrial Development Organization, No E.74.II.A.7, 1973.

UNIDO: Information Sources on the Pharmaceutical Industry. New York: United Nations Industrial Development Organization, 1976.

UNIDO: Investment Promotion and Industrial Financing -- Guide to Training Opportunities for Industrial Development. New York: United Nations Industrial Development Organization, 1977.

UNIDO: Manual for the Preparation of Industrial Feasibility Studies. New York: United Nations Industrial Development Organization, 1978.

UNIDO: Appropriate Industrial Technology for Drugs and Pharmaceuticals. New York: United Nations Industrial Development Organization, Monographs on Appropriate Industrial Technology No. 10, 1980.

Wortzel, L.H.: Technology Transfer in the Pharmaceutical Industry. New York: United Nations Institute for Training and Research, 1971.

---

* For topics related to Quality Control, see Chapter III.D. References.

Appendix III.F.1.

Sources of Technical Assistance for Local Production

The following list of potential sources of pharmaceutical production advice should not be considered to be all-inclusive, nor should it be taken as an endorsement. Potential advisors contacted through this or any other listing should be evaluated on an individual basis according to the needs of the program and references from related past projects.

a. International Assistance Agencies

UNIDO

United Nations Industrial Development Organization
Pharmaceutical Industries Unit
Chemical Industries Section
Industrial Operations Division
Vienna International Centre
P.O. Box 300, A-1400
Vienna, Austria
CABLE: UNIDO, VIENNA

Actively promoting local production of pharmaceuticals through meetings and publications. Source for technical advice. Has arranged tours of existing facilities, training programs, and technical consultants.

WHO

World Health Organization
Drug Policies and Management
1211 - Geneva 27, Switzerland
CABLE: UNISANTE, GENEVA

Will arrange some fellowships and other training opportunities for pharmaceutical personnel. Can assist in locating technical consultants with expertise in specific areas. Developing plans for basic pharmaceutical plants.

UNDP

United Nations Development Programme
Division of Information
One United Nations Plaza
New York, N.Y. 10017
CABLE: UNDEVPRO, NEW YORK

Contributes money towards development of technology; may subsidize the purchase of equipment and provide technical consultants.

UNCTAD
United Nations Conference on Trade and Development
Technology Division
Palais des Nations
1211 - Geneva 10, Switzerland
CABLE: UNATIONS, GENEVA

Involved in transfer-of-technology issues, has informed governments about changes in regulation affecting international trade; assists governments with procurement. Has developed a case study of the pharmaceutical industry.

UNITAR
United Nations Institute for Training and Research
United Nations
New York, N.Y. 10017
CABLE: UNATIONS, NEW YORK

Conducts seminars in procurement and warehousing, though not specific to pharmaceuticals.

UNCTNC
United Nations Centre on Transnational Corporations
605 Third Avenue
New York, N.Y. 10017
CABLE: UNATIONS, NEW YORK

Engaged primarily in research and dissemination of information on laws and regulations affecting transnational corporations and developing countries. Can advise LDC governments to improve their capabilities in negotiating with corporations on transfer-of-technology issues. Has done pharmaceutical study.

b. Industrial Consultants

Crown Agents for Overseas Governments and Administrations
4 Millbank Westminster
London SW1P 3JD, England
CABLE: CROWN LONDON SW1

Semi-public British institution which renders services to principals in the public sector of many developing countries formerly dependent on Britain. For countries developing local production facilities, Crown Agents has advised on the choice of equipment and arranged the purchase and occasionally the installation.

International Dispensary Association
P.O. Box 3098
1003 AB Amsterdam, The Netherlands
CABLE: IDAHQ

Responds to requests for assistance from developing countries, as well as from development organizations and donor agencies. Services have included feasibility studies, assistance in the procurement of pharmaceutical raw materials, transportation of pharmaceuticals and raw materials, support of initiatives for the improvement of distribution systems, and information services.

Pharmaceutical Production Consultancy
49 Frederick Road
Edgbaston
Birmingham B15 1HN, England
CABLE: HEWTEKT, BIRMINGHAM

Services include feasibility studies for local manufacture of pharmaceuticals, site selection, planning and design of facilities, quality control, staffing, management, and start-up, with special attention to tailoring programs to individual circumstances. Individual members of the Consultancy have much experience in the design and establishment of laboratories and manufacturing facilities in developing countries.

c. Quality Control, Plant Management, Production Staff Training, and Other Consultants

Arthur G. McKee & Company
10 South Riverside Plaza
Chicago, Illinois 60606
U.S.A.

Provides engineering and construction services for pharmaceutical industries - in particular, feasibility studies (site evaluation and capital cost estimates), process design, engineering, construction, and plant start-up assistance.

The Battles Co., Inc.
64 Grant Avenue
Carteret, New Jersey 07008
U.S.A.

Small firm active in the pharmaceutical field outside the U.S.A. Services include the procurement of raw materials and equipment, plant construction, quality control development, packaging, and licensing and patent negotiations. Has undertaken projects through UNIDO.

Dr. J.G. Davis and Partners
52 London Road
Reading, Berks RG1, 5AS
England

Consultant bacteriologist and chemists, with expertise in quality control testing of pharmaceutical products.

Harold A. Frediani
R.D. 4
Cazenovia, New York 13035
U.S.A.

Consultant (and associates) with experience in all phases of pharmaceutical production, quality assurance, automated and instrumental analytical methods, pilot plant operations, record-keeping, labels, package inserts; has developed an illustrated lecture series entitled "Sterile Operations in the Pharmaceutical Industry", designed to properly orient personnel involved in the development and production of injectable pharmaceuticals.

Indian Drugs and Pharmaceuticals Limited
N 12, NDSE, Part I
New Delhi 49, India
CABLE: INDRAPHARM

Consulting capability in drugs and pharmaceutical manufacture, training, and quality control.

Institute of Drug Technology Limited
381 Royal Parade
Parkville
Victoria, Australia 3052

Manufactures raw material drugs, also dosage forms and allied products: coated enzymes; antibiotics; conducting and sonic gels; flavored and unflavored suspensions; steroid ointments of high bioavailability; wide variety of tablet formulations, especially effervescent products. These are commercially available within Australia and internationally. IDT can also provide stability studies and registration documentation. Services available by contractual arrangement.

Intercon Research Associates Ltd.
1219 Howard Street
Evanston, Illinois 60202
U.S.A.

Experienced in the transfer of technology in the pharmaceutical manufacturing sector, able to assist local organizations in establishing, upgrading, and diversifying their technology base. Services include all aspects of establishing a manufacturing capability, licensing, and joint venture.

Nitson Laboratories
Road No. 22
Wagle Industrial Estate
Thana 400604
Bombay, India

Consulting capability in bulk drugs process development, manufacture cost reduction and improvement, and pilot plant operations.

Washington Reference Laboratory, Inc.
2614 Pittman Drive
Silver Spring, Maryland 20910
U.S.A.

Non-profit regional reference laboratory with expertise in pharmaceutical control. Has established laboratories and trained personnel in several countries. Developed the first hospital unit-dose packaging service in the world.

Roger Williams
Technical and Economic Services, Inc.
34 Washington Road
P.O. Box 426
Princeton, New Jersey 08540
U.S.A.

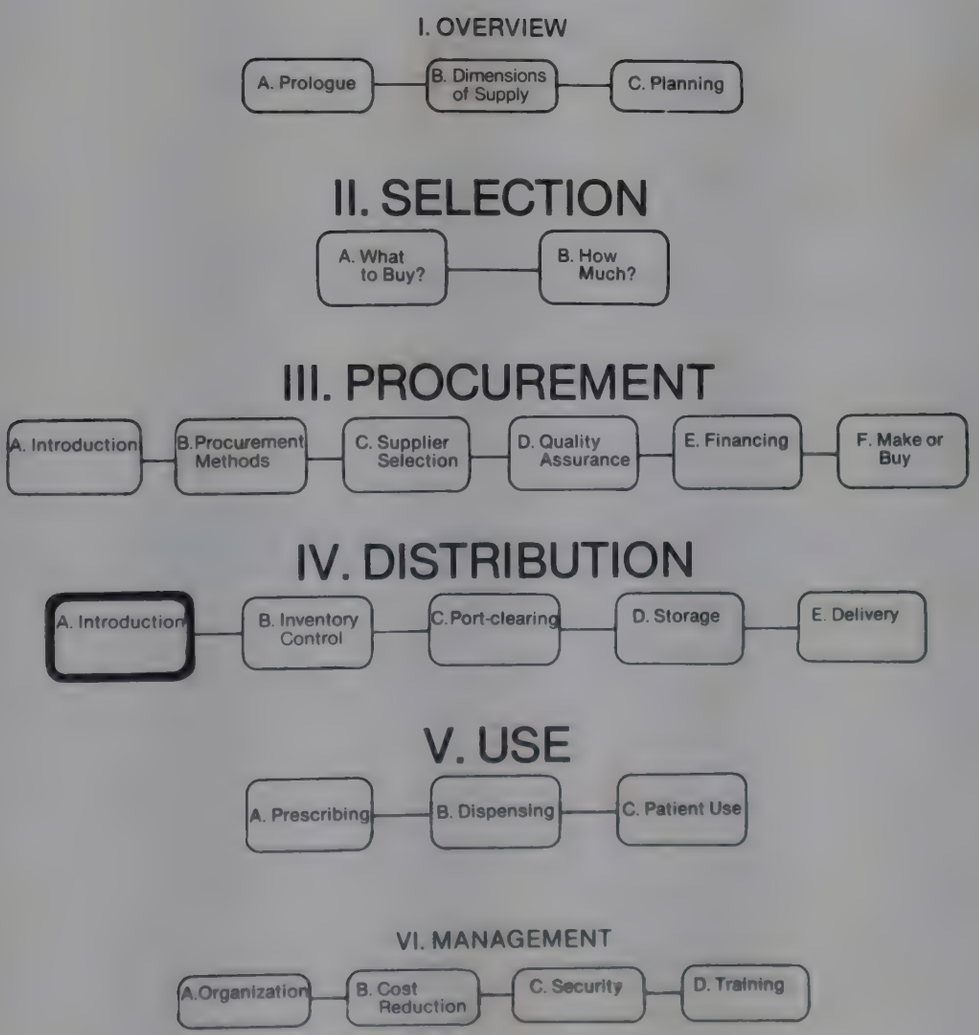
Consulting capability in the following areas: procurement of raw materials, quality control, packaging, licensing, and patent negotiations. Staff available for working in Latin America, South Africa, and Australia.

University of the Philippines System
Philippine Executive Academy
Padre Faura, Manila, Philippines

Consulting capability in organization development and management studies, including systems and procedures.

Chapter IV.A.

Introduction to the Distribution Cycle



	Page
1. ACTIVITIES IN THE DISTRIBUTION CYCLE	277
Drug Procurement	
Port-Clearing	
Receipt and Inspection	
Inventory Control	
Storage	
Requisition of Supplies	
Delivery	
Dispensing to Patients	
Consumption Reporting	
2. DESIGNING OR RE-DESIGNING A DISTRIBUTION NETWORK	280
a. Basic System Design Characteristics	280
b. Information System	280
c. Storage	284
d. Delivery	284
3. CHARACTERISTICS OF A WELL-RUN DISTRIBUTION SYSTEM	284
SUMMARY	285
REFERENCES	286

Introduction to the Distribution Cycle

Once the entire procurement cycle has been completed and the supplies have arrived in the country or are ready for delivery from a local supplier, the distribution network begins its work. Within the distribution cycle fall all of the activities required to receive drugs from the supplier and to move them safely, securely, and expeditiously to the many points in the health care system at which the drugs will be dispensed to patients.

The distribution network often develops in a somewhat haphazard, unplanned way. Storage points are determined by availability and historical exigencies, rather than by considerations of distribution efficiency. Record-keeping and inventory control may be minimal or non-existent. Where record-keeping systems exist, they often vary from institution to institution, making it difficult to collect consistent information with which to forecast drug needs. Transport of drugs from central facilities to peripheral dispensing points is sometimes extremely difficult because of the limited availability of railways, roads, vehicles, or other needed conveyances. The effects of these limitations are magnified when a large proportion of the available transportation resources are used for "emergency" deliveries necessitated by stockouts resulting from inadequate inventory planning and poor delivery scheduling.

Whether a distribution system already exists or one needs to be established as part of a new program, systematic planning is essential for the efficient use of invariably limited storage, transportation, and human resources. The key elements in the design of a new system or re-design of an old system are the storage points, the modes of transportation, the information system, and the materials handling procedures.

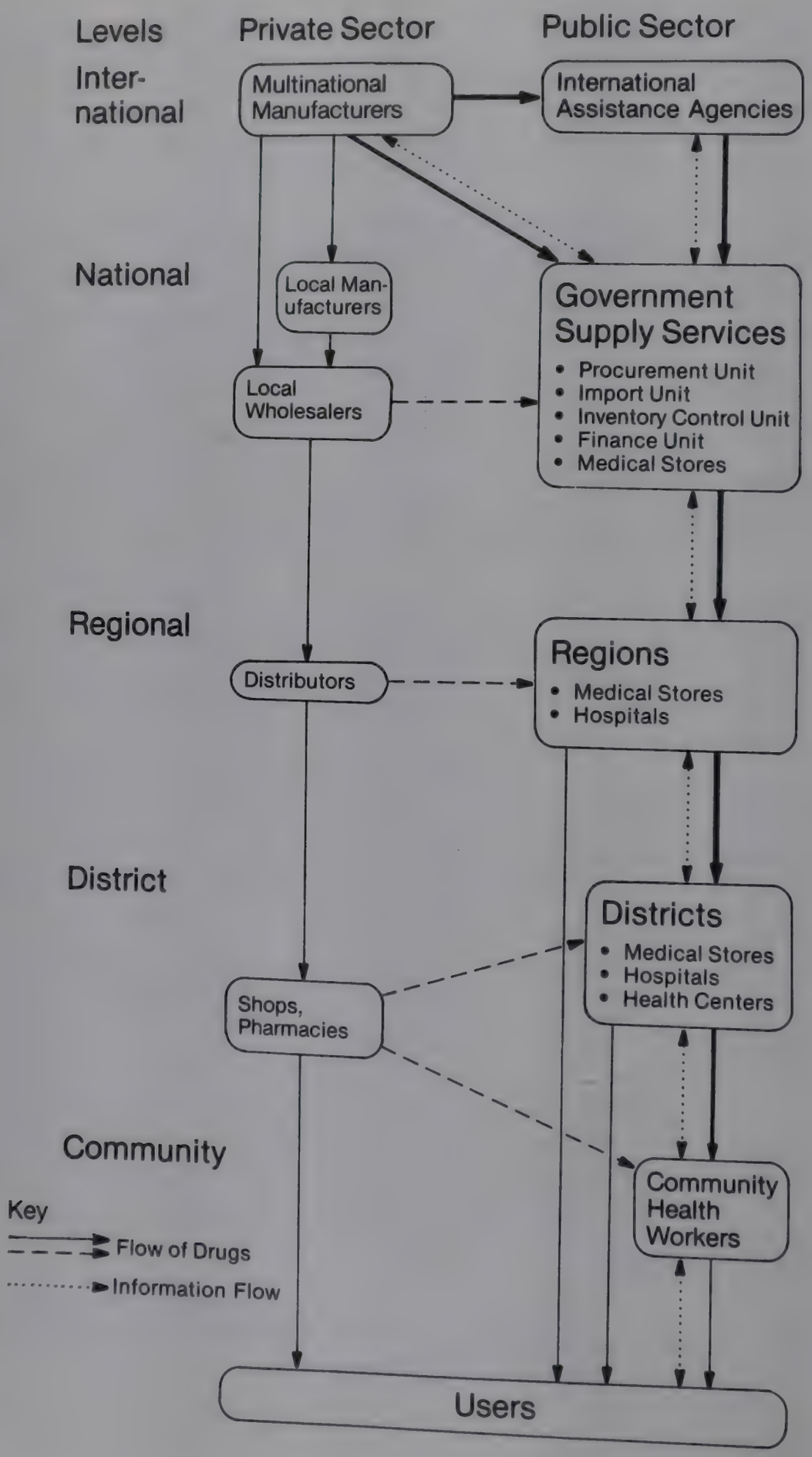
Figure IV.A.1. shows the flow of drugs and information in a typical drug supply system. Where commercial drug supply systems exist in parallel with public health supply systems, interaction between the two systems may occur at any level. Often procurement for the public program occurs only at the national level; distribution to regional, district, and community facilities is then run entirely by the public health program. In other areas, procurement from commercial sources (pharmacies, shops, etc.) occurs at all levels in the system. In still other programs, procurement contracts are negotiated at the national level, but distribution to hospitals and major health centers is done directly by the suppliers.

For completeness, the following four chapters describe distribution activities as if all were under the direction of a central drug supply program. Obviously this is not commonly the case, and it should not be assumed that a centralized distribution system is always preferable. Nevertheless, the major distribution activities, as described, should be understood by anyone involved in the drug supply process.

Assessment Guide IV.A. provides an informal self-assessment of distribution activities. It is intended to help provide an understanding of the structure and operation of existing distribution activities.

Figure IV.A.1.

Typical Public Drug Distribution System



ASSESSMENT GUIDE IV.A.
Evaluating the Distribution System

- How often are there stockouts (shortages) at the central warehouse? At regional stores? At individual peripheral points?
- What percent of dated products exceed their expiration date before being consumed? Are there procedures to minimize these losses?
- What are the stock levels at each point in the system? Are these high, low? What are the holding costs associated with this inventory? Do stock levels vary from one part of the country to another? From dry season to rainy season?
- What percent of deliveries are routine (weekly, monthly, quarterly, etc.) and what percent are "emergency" deliveries? Are limited transportation resources being used unnecessarily for "emergency" deliveries?
- How is the system arranged? How many levels in the distribution system are there? How far apart in time and distance are the levels of the system?
- What kinds of transportation are used? Are these modes of transportation mandated by government policy or arrangement? What alternatives are available? What does transportation cost? Is transportation wasted on dead backhauls (returning empty from a delivery)?

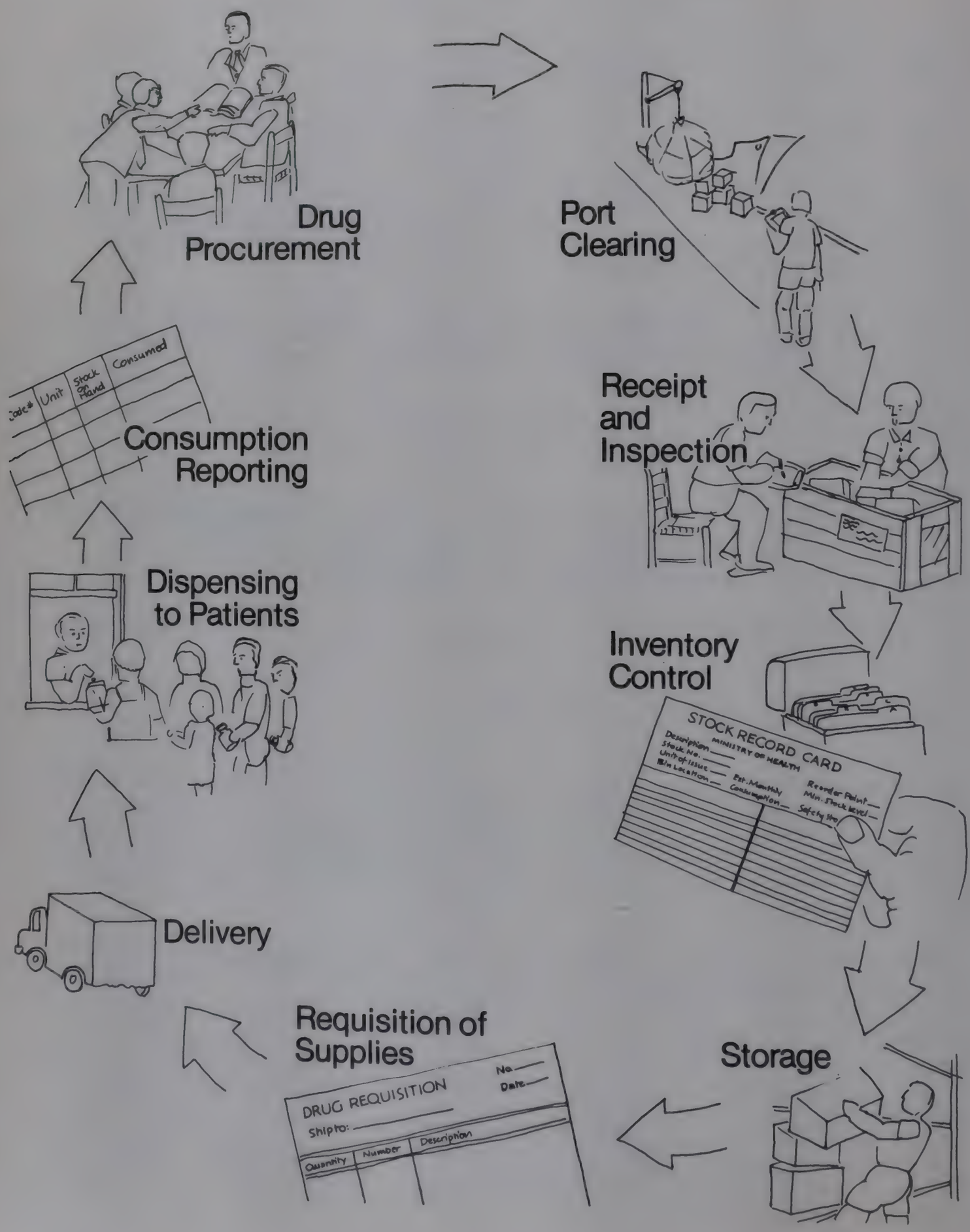
1. ACTIVITIES IN THE DISTRIBUTION CYCLE

In an on-going public health program, distribution is a cyclic process in which the same sequence of activities occurs repeatedly to provide a steady supply of drugs to hospitals, health centers, and community health workers. The major activities of the distribution cycle, which are described in detail in the following chapters, are summarized in Figure IV.A.2. Briefly, these activities include the following:

(1) Drug Procurement (Section III.) -- The distribution cycle intersects the procurement cycle at the point at which drugs have been acquired and have arrived at a port or are available for delivery to the public health program.

(2) Port-Clearing (Chapter IV.C.) -- Unless drugs are supplied from local warehouses or the importation process is handled entirely by local agents, port-clearing is the first step in making drugs available for distribution. It involves identifying shipments as soon as they arrive in port, processing all importation documents, completing any customs requirements, assuring proper storage of drugs until they are removed from the port, surveying the

Figure IV.A.2.
The Distribution Cycle



shipment for signs of damage, and collecting the drugs as soon as they have been cleared.

(3) Receipt and Inspection (Chapter IV.D.) -- When drugs are first delivered from the port or directly from a supplier to the warehouse, they must be kept separate from the other stock until the warehouse staff has performed a complete formal inspection of the shipment. Standard inspection procedures should uncover any damages and assure that the supplier has fulfilled the contract in terms of quantity, packaging, labeling, type of drug, dosage form, and any special requirements. Prompt, accurate shipment inspection is essential if all legitimate insurance claims are to be made and if suppliers are to be held to their contracts.

(4) Inventory Control (Chapter IV.B.) -- The establishment and maintenance of effective inventory records and procedures is the basis for coordinating the flow of drugs through the distribution system. Record-keeping should be detailed enough to provide an "audit trail" for government officials, donor agencies, or managers of the drug supply system to trace the flow of drugs and funds through the system. The inventory control system is also the basis for requisitioning and issuing drugs, for financial accounting, and for preparing consumption reports necessary for future procurement. An inventory control system should exist at all levels in the health program, but the type of system should be adapted to the training and needs of personnel at each level.

(5) Storage (Chapter IV.D.) -- Storage facilities range from large, sometimes mechanized warehouses at the national level to small wooden boxes sitting in health centers or carried by community health workers. Proper organization and maintenance of storage facilities ensures that drug quality is maintained, theft is minimized, and drugs are efficiently issued to other facilities or dispensed to patients.

(6) Requisition of Supplies (Chapter IV.B.) -- Forms and procedures for requisitioning supplies from storage facilities are part of the information system. The exact forms and procedures may vary from country to country and from one level to another within the same country, but in every instance they should serve to expedite, rather than hinder, the distribution process. Arrangements for requisitioning supplies should also facilitate inventory control, provide an audit trail for tracing the flow of drugs, contribute to financial accounting where necessary, and supply a listing of drugs issued which can be used to assure that drugs are not lost in transit.

(7) Delivery (Chapter IV.E.) -- Within the country, drugs may be transported by air, by sea, by railroad, or by a variety of vehicles. Punctual and economic transport of supplies requires that distribution managers select the modes of transportation carefully and schedule deliveries realistically, but systematically. Vehicle breakdowns, stockouts of repair parts, seasonal variations in access routes, safety along specific supply lines, and other local factors are all included in the planning process.

(8) Dispensing to Patients (Section V.) -- The distribution process achieves its ultimate purpose when drugs reach hospital wards, outpatient clinics, health centers, or community health workers, and are appropriately prescribed and dispensed to the patients.

(9) Consumption Reporting (Chapter IV.B.) -- The closing link in the distribution chain is the flow of consumption information back up the distribution system to the offices responsible for procurement. If adequate inventory and requisition records are kept, the generation of consumption reports should be an easy process.

2. DESIGNING OR RE-DESIGNING A DISTRIBUTION NETWORK

Designing a new distribution system or substantially re-designing an existing distribution network requires a step-by-step planning process, as described in Chapter I.C. The significant design characteristics for a distribution network (see Figure IV.A.3.) are considered in detail in subsequent chapters and will be mentioned only briefly at this point.

a. Basic System Design Characteristics

Basic characteristics of a distribution system include the degree of centralization, the number of levels in the system, and the geographic or population coverage. In a decentralized system, supplies are delivered to regional, district, or local warehouses and pharmacies; management of the deliveries may also be decentralized, or it may involve a central office which simply oversees the process. The levels of a distribution network refer to the number of points or layers at which stock is kept. A system which receives, stores, and issues drugs from a central medical store, regional warehouses, district hospitals, and health centers would be a four-level system. The number of levels in the system is an important determinant of the total cost of operating the distribution system as well as the efficiency with which drugs are delivered.

Geographic and population coverage refers to the area and people served by the system. Pilot programs often serve only one region and require a different degree of organization than do national programs. The system may also be restricted by government or donor policy to serving only specific sub-populations such as mothers and children.

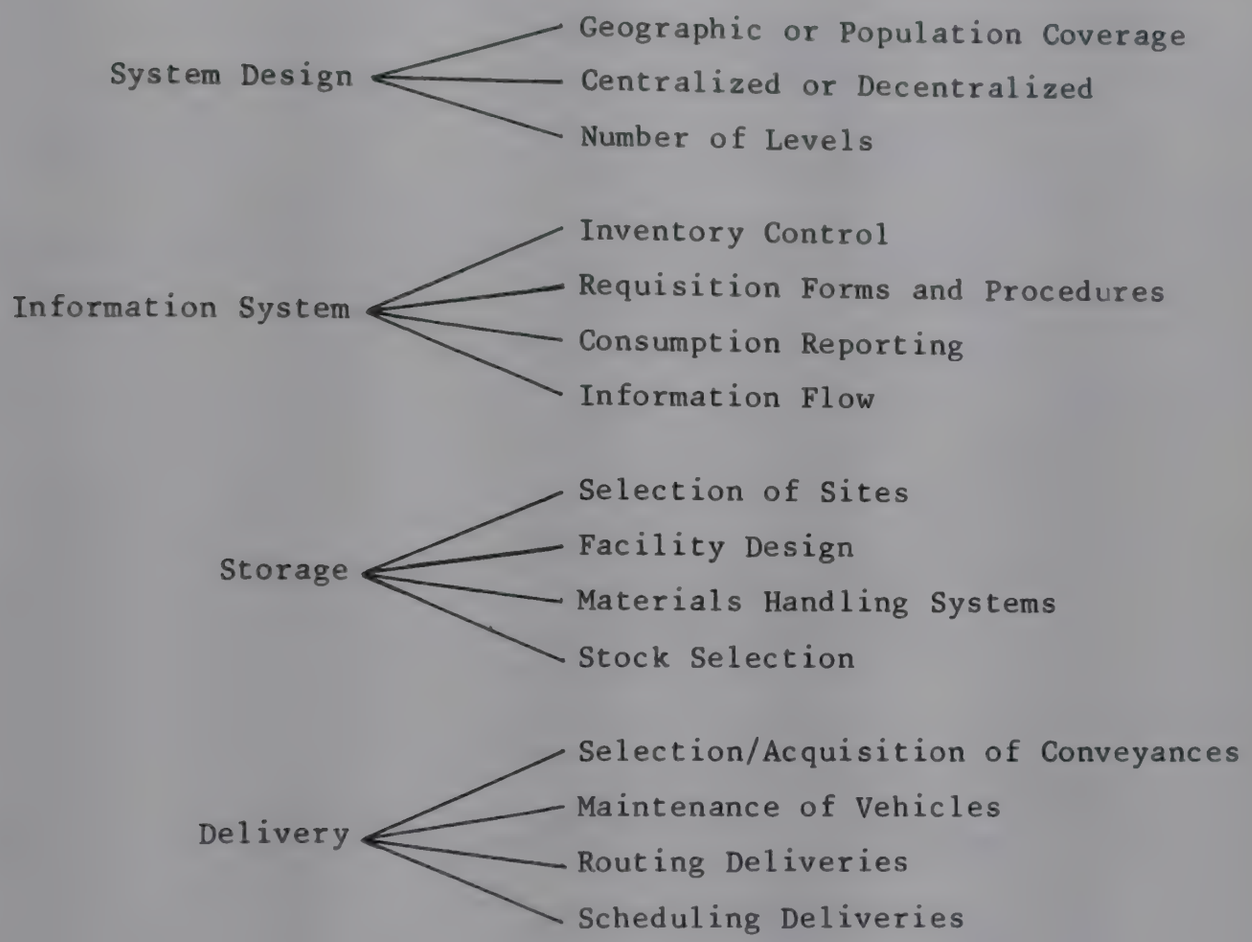
b. Information System

Good information is important for the coordination of the distribution network. The information system consists of a set of documents used to record inventory levels, receipt and issue of drugs, and drug consumption. It also includes the procedures which govern the use of those forms and the flow of information up and down the distribution network.

It is relatively easy to imagine and follow the one-way flow of drugs through the supply pipeline from the central medical store to regional or district stores and, finally, to the hospitals, health centers, and village health workers. It is far more difficult to understand and follow the complementary flow of forms and reports which are needed to coordinate drug distribution.

Figure IV.A.3.

Distribution Network Design Characteristics



In the preceding chapters on procurement and in the following chapters on distribution, numerous forms, records, and reports are mentioned. These documents are the fabric of the supply information system. To clarify the structure of this information system, the names, purposes, sources, and flow of these documents are summarized in Figures IV.A.4. and IV.A.5. The reader is encouraged to keep these figures in mind and refer to them when new forms, records, or reports are mentioned.

Forms are documents which move from one unit to another, carrying specific information about drug needs, shipments, movement of drugs, and similar subjects. Copies of forms are filed at various points in the distribution network and, thereby, help to form the "audit trail" for tracing the flow of drugs and funds. Records are maintained as card files, ledgers, or in folders to record specific information for use by a single unit. Reports are prepared quarterly, semiannually, and/or annually to summarize drug consumption and expenditures. Individual health facilities report to district offices, which report to regional offices, which, in

Figure IV.A.4.

Flow of Documents in a Basic Distribution Information System

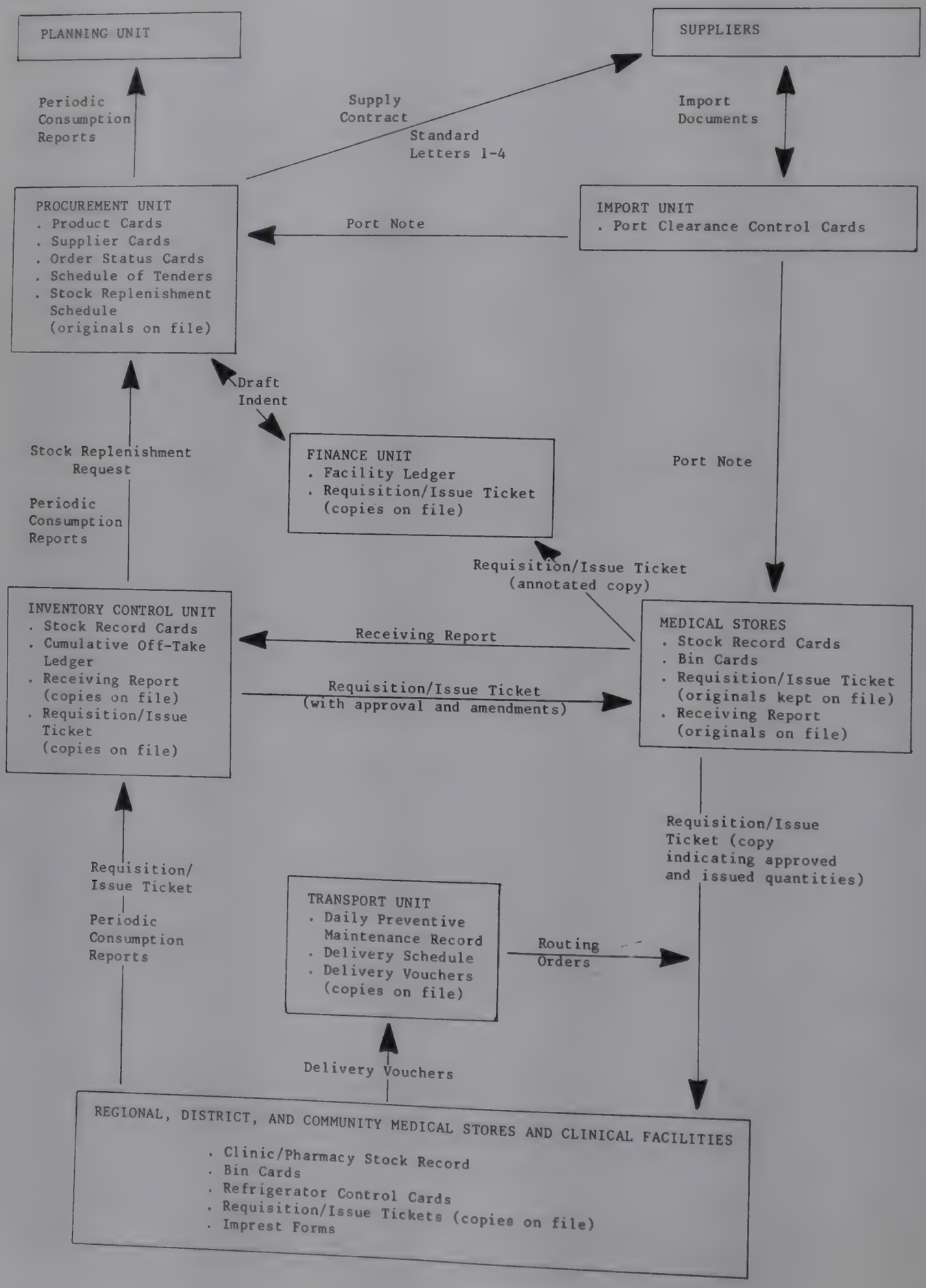


Figure IV.A.5.

Forms and Records for a Basic Distribution Information System

DOCUMENT -- Description	Originated by/ Maintained by	Manual Reference
FORMS:		
Supply Contract -- Statement of the terms of supply, usually publicized with the Call for Offers, specifying exact drug requirements, dosage forms, quality standards, labeling and packaging, delivery date, and other supply details.	Procurement Unit	Chapter III.B. Figure III.B.5.
Standard Letters 1-4 -- Form letters used in correspondence with suppliers to provide and obtain information regarding outstanding orders.	Procurement Unit	Chapter III.B. Appendix III.B.2.
Import Documents -- Used to confirm the supply contract, guarantee payment, and certify the quantity and quality of shipment contents, and to provide other types of trade information.	Procurement, Supplier, Shipper, Banks	Chapter IV.C. Figures IV.C.1. and IV.C.2.
Port Note -- Notification from Import Unit to Procurement and Medical Stores that a specific shipment has arrived and has been cleared from port.	Import Unit	(no sample)
Receiving Report -- Notification to Inventory Control that a specific shipment has been received; indicates damages, short-shipments, etc.	Medical Stores	Chapter IV.D. Appendix IV.D.2.
Requisition/Issue Ticket -- Request for specific quantities of standard items from Medical Stores; amended by Inventory Conrol if stocks low; filled by Medical Stores. Copies provide audit trail. Return copy is packing slip.	Medical Stores, Health Facilities	Chapter IV.D. Appendix IV.D.3. Figure IV.D.11.
Stock Replenishment Request -- Request to Procurement to begin the procurement cycle for specific items. Sent at reorder level or reorder interval.	Inventory Control	Chapter IV.B. Appendix IV.D.1.
Draft Indent -- Proposed order quantities for a single procurement cycle. Finance Unit estimates cost and adjusts if needs exceed available funds.	Procurement	(no sample)
Routing Order -- Delivery order for drivers; provides a record of vehicle movements, indicates the order of deliveries (planned to minimize travel).	Transport Unit	Chapter IV.E. Figure IV.E.4.
Delivery Voucher -- Signed receipt indicating that a specific shipment of drugs has been delivered intact.	Medical Stores, Health Facilities	Chapter IV.E. Appendix IV.D.5.
Imprest Forms -- Simplified supply requisitions for use by smaller clinical facilities and individual health workers.	Health Centers and Workers	Chapter IV.B. Figure IV.B.9.
RECORDS:		
Product Cards -- Contain product specifications and supplier history for each item. Used to prepare bid specifications and select suppliers.	Procurement Unit	Chapter III.C. Figure III.C.5.
Supplier Cards -- Record experiences with individual suppliers, including delivery record, adherence to contract, drug and packaging quality, other performance factors. Used in supplier selection.	Procurement Unit	Chapter III.C. Figure III.C.4.
Order Status Cards -- Used to monitor the status of outstanding orders to reduce lead times, supplier defaults, and port delays.	Procurement Unit	Chapter III.B. C'try Study III.B.2.
Schedules of Tenders -- Summaries of offers from each supplier on each product in a tender purchase.	Procurement Unit	Chapter III.C. Figure III.C.6.
Port Clearance Control Cards -- Used for a manual control system to monitor port-clearing activities and, thereby, shorten port delays.	Import Unit	Chapter IV.C. C'try Study IV.C.1.
Stock Record Cards -- Cards or a ledger used to record stock balances, issues, receipts, and outstanding orders. Essential in inventory decisions such as when and how much to order.	Medical Stores, Health Facilities	Chapter IV.B. Figure IV.B.4. Figure IV.B.8.
Bin Cards -- Similar to Stock Record Cards, but kept in medical stores with the physical stock to record supply movement in and out of the stores.	Medical Stores	Chapter IV.D. Appendix IV.D.4.
Facility Ledger, Cumulative Off-Take Ledger -- Records indicating the quantity and cost of drugs issued to individual facilities. Used for budgeting, billing, and/or estimating future needs.	Finance Unit, Inventory Control	Chapter IV.D. (no sample)
Daily Preventive Maintenance Record -- Checklist of daily vehicle maintenance activities used to promote preventive maintenance.	Transport Unit	Chapter IV.E. Figure IV.E.2.
Delivery Schedule -- Monthly timetable for requisitions and deliveries. Prepared for maximum staff and vehicle efficiency.	Transport Unit	Chapter IV.E. Figure IV.E.3
Refrigerator Control Cards -- Temperature and maintenance log to assure proper cold chain storage.	Clinical Facilities	Chapter IV.D. Appendix IV.D.6.

turn, report to the central office. Such reports are used to project future drug needs, to revise budgets, and to assess drug utilization.

The documents described in this manual are meant as examples. Each supply system must adapt its information system to suit its own requirements. The forms presented in the manual may be completely adequate as they appear, some may need modification, others may be unnecessary, and additional ones may be required to suit special information needs.

When a new drug supply program is initiated or an old program undergoes major revision, a complete information system should be established as part of the basic planning process. All necessary forms should be available and all staff should be trained in the use of these forms before drugs start moving through the system. Without this type of preparation, recording of drug consumption and forecasting of drug needs quickly breaks down.

c. Storage

Storage planning includes the selection of storage sites, the design of the specific storage facilities (ranging from wooden boxes to large warehouses) the establishment of systems for handling drugs within each storage site, and determination of the types of drugs to be kept at each storage location. The selection of storage sites may be limited by the location of existing health facilities. Nevertheless, all options for locating distribution points should be considered and evaluated in light of transportation options.

Once specific storage sites are selected, construction or renovation plans should take into consideration special storage conditions required for certain products, the need to move large volumes of material efficiently, and theft control.

d. Delivery

Delivery planning includes not only the selection of transportation modes and, if necessary, acquisition of vehicles or other conveyances, but also optimal use of available transportation through wise routing and scheduling of deliveries.

Transportation is frequently the least reliable link in the distribution system and the source of great frustration. Nevertheless, the systematic approach to transportation planning presented in Chapter IV.E. should help improve delivery efficiency, even if some problems remain.

3. CHARACTERISTICS OF A WELL-RUN DISTRIBUTION SYSTEM

Some specific performance measures for the distribution system are given in subsequent chapters (Chapters IV.D. and IV.E.), but, in general, a well-run distribution system should accomplish the following objectives:

- Store drugs under conditions which maintain the quality of drugs and packaging, and which allow easy access to individual drugs within the stores.

- Optimize inventory management with procedures which avert shortages, avoid overstocks, and minimize the amount of inventory needed to maintain a constant supply at each point in the distribution network.

- Locate drug stock points in a manner which makes optimal use of available storage facilities and at the same time facilitates delivery to peripheral facilties.

- Maintain accurate inventory records for forecasting future drug needs and auditing past consumption.

- Use available transportation resources as efficiently as possible through conscientious maintenance of vehicles and other conveyances, careful design of delivery routes, and realistic, but systematic scheduling of deliveries.

- Reduce pilferage and fraud with thorough inspection of drug shipments, adherence to specific routines for issuing and dispensing drugs, and establishment of a security system for storage and transportation.

- Minimize drug losses due to spoilage and expiration of dated products by using sound materials management practices.

The following four chapters deal with distribution activities, the performance of which largely determine the extent to which the preceding objectives are achieved. Chapter IV.B. discusses basic concepts in inventory control and describes in detail the inventory control procedures and forms for medical stores and health facilities, used at the central, regional, district, and local levels. Chapter IV.C. reviews the port-clearing process and suggests ways to expedite the process. Chapter IV.D. considers storage activities in detail, covering warehouse location, siting, design, staffing, and internal operation, as well as elements of cold chain storage. Finally, Chapter IV.E. outlines delivery strategies, emphasizing transportation planning, vehicle acquisition and maintenance, and efficient delivery routes and schedules.

SUMMARY

In an on-going public health program, distribution is a cyclic process which includes the following steps:

- drug procurement
- port-clearing
- receipt and inspection
- inventory control
- storage
- requisition of supplies
- delivery
- dispensing to patients
- consumption reporting

In designing a new distribution system or substantially re-designing an existing one, four characteristics to consider in detail are:

(1) System Design (geographic or population coverage, degree of centralization, number of levels in the system);

(2) Information System (inventory control, records and forms, consumption reports, information flow);

(3) Storage (selection of sites, facility design, materials handling systems, stock selection);

(4) Delivery (selection and acquisition of conveyances, maintenance of vehicles, routing and scheduling of deliveries).

A well-designed, well-managed distribution system should:

- maintain drug quality
- optimize inventory management
- make best use of available storage facilities
- provide information for forecasting future drug needs
- use available transportation resources as efficiently as possible
- reduce pilferage and fraud
- minimize spoilage and expiration of products.

CHAPTER IV.A. REFERENCES

Attwood, P.R.: Planning a Distribution System. London: Gower Press Limited, 1971.

Bowersox, D.J.: Logistical Management. New York: Macmillan Publishing Co., Inc., 1974.

Davis, G.M. and Brown, S.W.: Logistics Management. Lexington, MA: D.C. Heath and Company, 1974.

Hart, R.J. and Marshall, F.S.V.: Wastage of Pharmaceuticals. The Lancet: 1239-1240, December, 1976.

Lane, N.S.: A Vital Link: Ensuring Supplies of Medical Equipment and Drugs Where Really Needed. WHO Chronicle 31: 404-407. Geneva: World Health Organization, 1977.

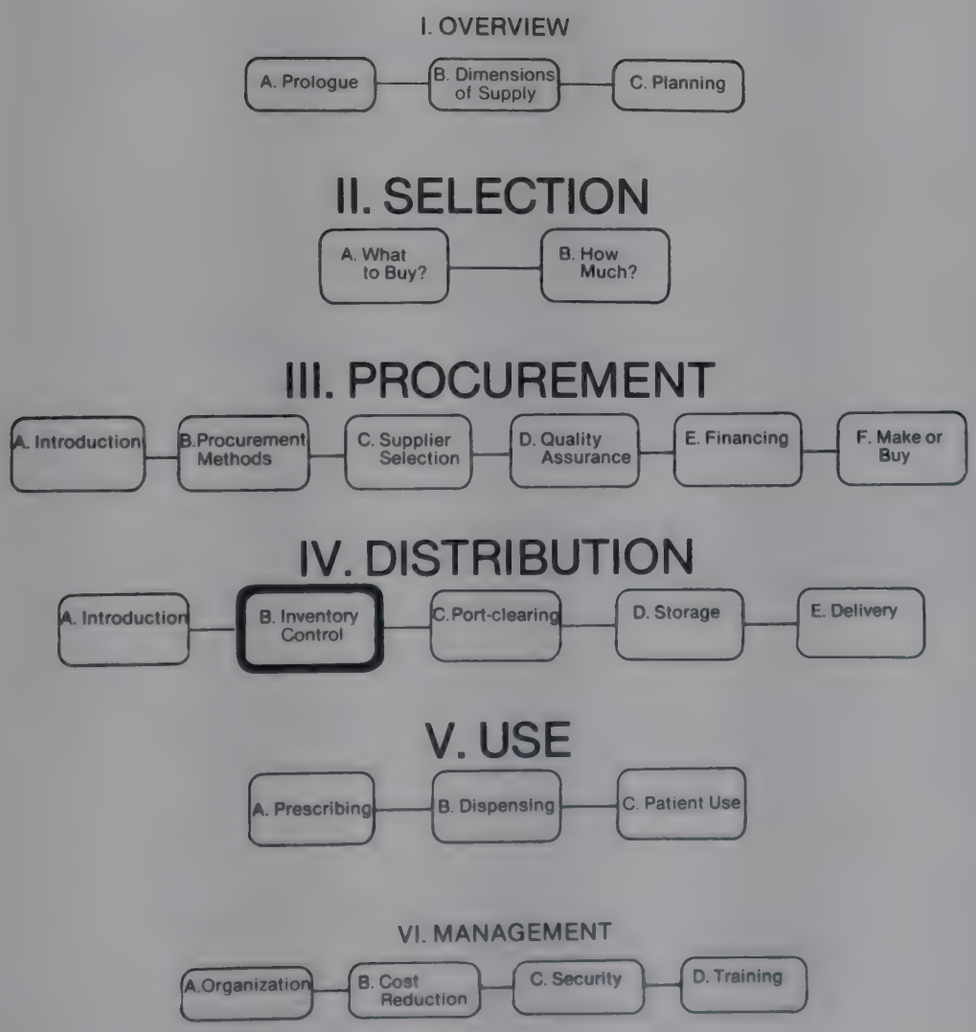
Lloyd, J.S.: Improving the Vaccine Cold Chain II; Progress Report December 1977. Geneva: World Health Organization, 1977.

cMahon, R. et al: On Being in Charge - A Guide for Middle-Level Management in Primary Health Care. Geneva: World Health Organization, 1980.

orld Health Organization: Expanded Programme on Immunization. Geneva: World Health Organization, EPI/G/77.1, 1977.

Chapter IV.B.

Inventory Control



	Page
1. BASIC CONCEPTS IN INVENTORY MANAGEMENT	291
a. Benefits of Inventory	291
b. Costs of Inventory	292
c. Working Stock, Safety Stock, and Service Level	294
d. Types of Inventory Control Systems	296
e. Stock Records	298
2. INVENTORY CONTROL AND PURCHASING AT THE CENTRAL LEVEL	301
a. Annual Purchasing	304
b. Scheduled Purchasing	305
c. Perpetual Purchasing	308
d. Modified Optional Replenishment	310
e. Choosing a Procurement Pattern	310
3. INVENTORY CONTROL AT THE REGIONAL AND DISTRICT LEVEL	311
4. STOCK CONTROL AT CLINICAL FACILITIES	313
a. Imprest System	314
b. The Two-Bin or Double-Shelf System	317
c. Visual Inventory Control	318
SUMMARY	318
REFERENCES	319
APPENDIX	
IV.B.1. Determination of Economic Order Interval and Economic Order Quantity	321

Inventory Control

Inventory, the stock on hand at any given time, is an essential part of ny supply system. Drug inventories exist to assure that when people are sick r need vaccination, the correct medicines are in the country and available at he right time at an accessible location. The total amount of inventory held t any one time at all points in the supply system can be substantial and its aintenance costly; therefore, efficient inventory management is crucial.

1. BASIC CONCEPTS IN INVENTORY MANAGEMENT

The classic inventory problem is balancing the benefits of holding inventory against the costs of doing so (see Figure IV.B.1.); this is the basis for understanding inventory control and procurement practices.

a. Benefits of Inventory

Inventory serves numerous important purposes, the most significant of which are the following:

(1) To Protect Against Uncertainty. Inventory absorbs fluctuations in both supply and demand, acting as a safety factor between the manufacturer and the patient. If deliveries are unexpectedly late anywhere along the line or if demand suddenly increases, as in an epidemic, sufficient inventory protects the patient from a stockout.

(2) To Permit Bulk Purchasing or Manufacture. Unit prices for drug purchases as well as manufactured items are generally lower when large quantities are involved. These quantities are held as inventory and distributed as needed.

(3) To Minimize Waiting Time. If each time a pill were needed up-country, it was individually requested from an overseas supplier, the lag between diagnosis and treatment would be many months. Stock distributed at points throughout the country increases the availability of drugs.

(4) To Increase Transportation Efficiency. Just as the waiting time would be long if each drug were ordered individually, the cost of transportation would rise if items were not shipped in bulk. Inventory exists to supply drug needs between shipments.

(5) To Anticipate Seasonal Fluctuations. Seasonal changes in demand for specific drugs are, in part, predictable. Inventories are built up in anticipation of increased demand and held at lower points during slack seasons.

Drug inventories serve these purposes at a price, often referred to as the holding cost or carrying cost of inventory.

ASSESSMENT GUIDE IV.B.
Inventory Control and Record-Keeping Procedures

- What inventory records exist at each level of the health care system? Who maintains these records? How accurate and how current are the records? How useful are these records? Do they supply the information needed for procurement and distribution decisions?

- How is the frequency and quantity of drug orders determined? Is there an inventory control system which is tied to the procurement process? If so, is this system effective in assuring regular ordering and receipt of adequate drug quantities (within prevailing financial constraints)?

- At the present time, how much stock is on hand at central storage facilities? At regional and district facilities? At hospital pharmacies, health centers, dispensaries, and other clinical facilities?

- What is the cost of maintaining this inventory in terms of warehouse and storeroom expense? In terms of losses due to expiration, spoilage, pilferage, or change of prescribing preferences? In terms of the tie-up of funds which might be used elsewhere?

- How were these inventory levels determined? By chance? By trial and error? Systematically using a standard inventory analysis system?

- How much of the current inventory at these facilities is considered to be "safety stock"? Is this amount of safety stock sufficient to prevent shortages of needed items? Is the safety stock the same for all items or is it higher for the more critically needed items?

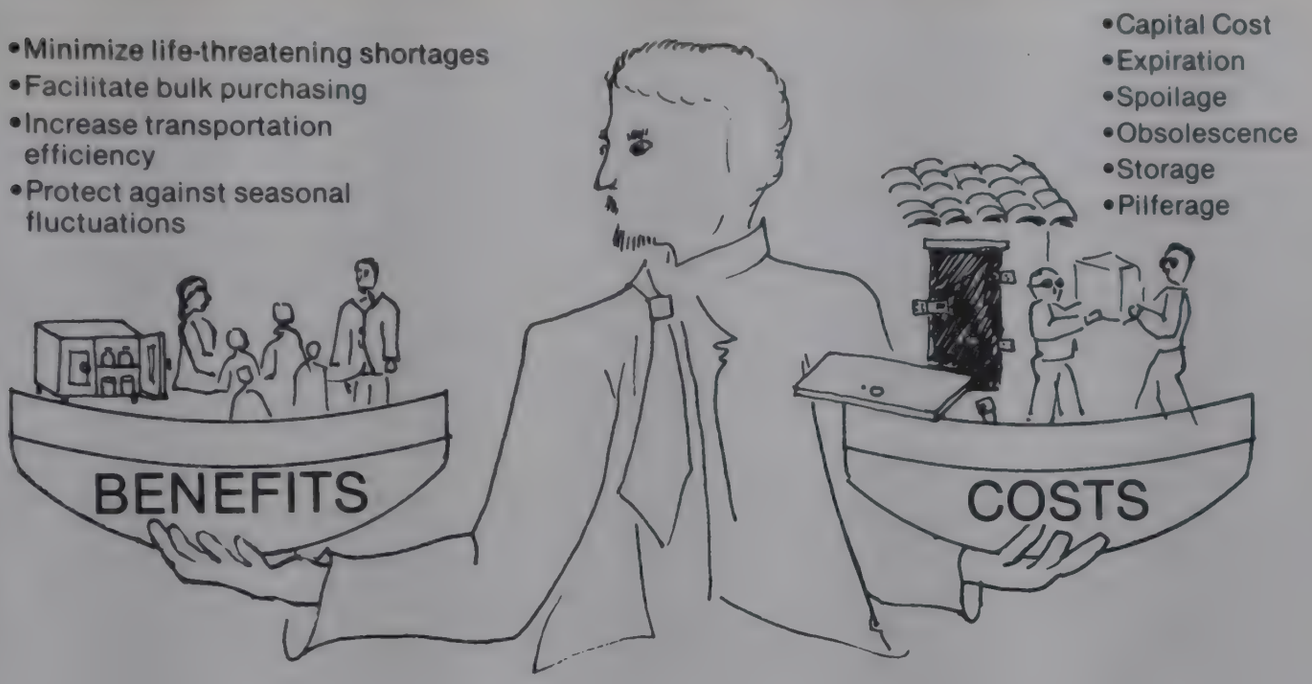
- What stock records are kept at health centers, aid posts, dispensaries, and other peripheral health care facilities? Are these records suited to the needs and record-keeping abilities of the health workers at these levels?

b. Costs of Inventory

Holding costs are usually expressed as a percent of the average inventory value. A typical holding cost for a commercial firm is 20 percent; because of some of the costs listed below, the holding cost for a government supply program may be considerably higher. Thus, a drug supply program which dispenses U.S.$2 million worth of drugs a year and maintains an average inventory of $1 million stored throughout the system may spend $200,000 to $500,000 a year simply to maintain the inventory -- a major portion of the total drug expenditure! Therefore, it is important to manage inventory efficiently and to minimize holding costs wherever possible.

Figure IV. B. 1.

The Inventory Problem: A Question of Balance



Capital Cost

Inventories are just like any other asset of an organization as they can account for a very large amount of capital. Often, inventories have to be financed through borrowings in the form of overdrafts or loans, for which high interest must be paid. On the other hand, if the organization uses its own funds to maintain inventories, these funds cannot be used elsewhere. Whether internal or external financing is employed, maintaining inventories is extremely costly. The actual cost will depend on the average level of inventory held and the interest rate. Considering that interest rates can be more than 20% per annum, the capital cost of maintaining inventories becomes a major expense.

Storage Costs

In addition to the cost of capital tied up as inventory, there are several other costs incurred. Some of these costs are proportional to the amount of stock in inventory; others are not.

- Stocking Cost -- This usually includes the costs of floor space, taxes, heat, electricity, maintenance of warehouse buildings, and security services, which can be considered generally as fixed costs in the short run. There are also some other costs such as insurance, cold room operation and materials handling costs, which depend largely on the amount of inventory held.

- Deterioration and Spoilage -- Many products deteriorate or spoil when stored for a long time. The nature and extent of deterioration varies from product to product. For pharmaceutical preparations, deterioration may necessitate scrapping the entire stock of an item. Often, the

extent of deterioration is proportional to the quantity in stock; the larger the inventory of a product, the higher the losses due to deterioration.

- Obsolescence -- Another factor which encourages smaller inventories is possible obsolescence of products. For drug supplies, this might be termed the "change of preference cost," since this category of expense arises largely from changes in prescribing patterns. Where drug supply is loosely controlled promotion of new products by pharmaceutical companies contributes to the obsolescence cost by encouraging physicians to use newer drugs, leaving unused stocks of the older alternatives. Where control is tighter, physicians may be forced to deplete the stock of the old drug -- over which the newer drug usually has few advantages -- before the new drug is released. The obsolescence cost can sometimes be reduced through credit-for-return arrangements with suppliers.

- Expiration of Products -- Pharmaceutical products generally bear an expiration date by which they ought to be consumed or destroyed. In practice, policies regarding disposal or return of outdated products vary from country to country and, within countries, from pharmacist to pharmacist. It is not unusual to find that each year three to five percent of a program's inventory has expired. A discussion of shelf life appears in Chapter III.D. and techniques for minimizing the volume of expired drugs are described in Chapter VI.B.

- Pilferage -- Introduction of strict security systems certainly helps to minimize pilferage but it is doubtful whether theft can be completely eliminated. Often, pilferage is confined to high value, small size products easily removed from stores without detection. In countries where average wages are generally low, pilferage can be a major problem which adds considerably to the cost of carrying inventories. Chapter VI.C. is devoted entirely to security systems.

While it is quite clear that inventories perform a vital function, carrying costs make it extremely important to maintain the inventory at proper levels at all times through the use of suitable inventory control systems.

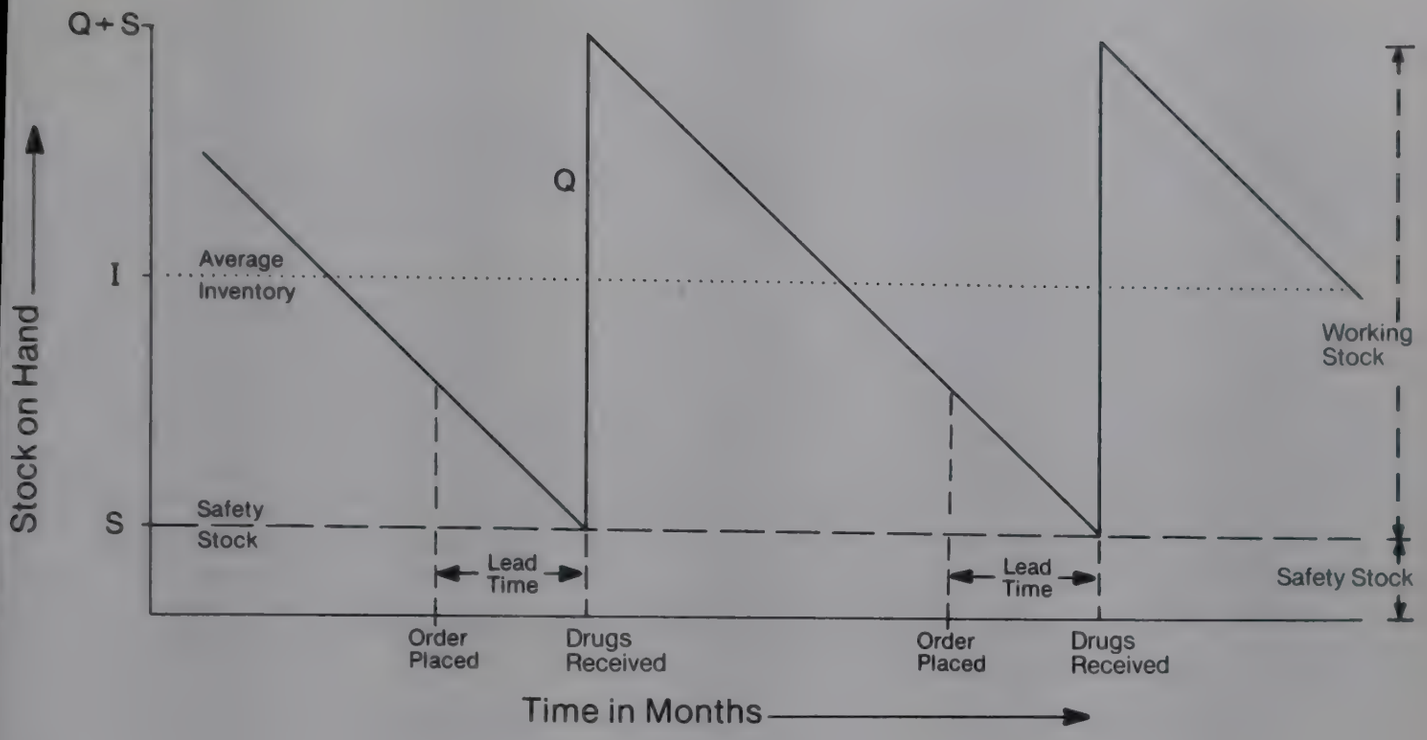
c. Working Stock, Safety Stock, and Service Level

The ideal inventory model is shown in Figure IV.B.2. The stock on hand consists of two components, the working stock and the safety stock. Working Stock varies from zero to the order quantity (Q) and represents the stock which is used to satisfy demand between deliveries. Safety Stock (S), also called reserve stock, buffer stock, or fluctuation stock, exists to protect against stockouts which would otherwise occur when deliveries are delayed for any reason or the working stock is consumed at an unexpectedly high rate.

In the ideal model, drugs are issued in response to demand and the stock on hand steadily declines until the point at which an order must be placed. Following the lead time period, during which all the activities of the procurement cycle are performed, the quantity ordered (Q) is received and the inventory level is back to its starting maximum point (Q+S).

Figure IV.B.2.

Ideal Inventory Model



From Figure IV.B.2. it is apparent that the average working stock is one-half of the order quantity.

Average working stock = 1/2 Q.

The average inventory (I) or average stock on hand is the safety stock plus the average working stock.

Average inventory = I = S + 1/2 Q.

To reduce the average inventory and, thereby, reduce the inventory holding costs, either the working stock, the safety stock, or both should be lowered.

When drugs are used at a constant rate, the line in Figure IV.B.2. representing stock on hand declines with a constant slope. The working stock can be reduced only by placing smaller orders (reduce the size of Q) more frequently. Determinants of order size and frequency are considered in the next section.

The average inventory can also be reduced by cutting the safety stock, but this increases the chance of stockouts. In commercial enterprises, the optimum safety stock can be estimated with standard formulas using knowledge about demand patterns, the inventory costs, sales income lost from stockouts, and other factors. In pharmaceutical supply, as in other public enterprises, there is no financial optimum. Instead, the cost of additional safety stock must be weighed against the potential health impact of stockouts.

The effect of safety stocks can be measured in terms of the service level, which is described by the percent of requests which can be filled from stock on hand. For example, a 95% service level means that a specific drug is in stock 95% of the time, on the average. The reverse of this is the stockout frequency. With a 95% service level, the stockout frequency is about 5%. The amount of safety stock required to assure a given service level is based on mathematical probabilities and, as demonstrated in Figure IV.B.3., this amount increases steeply with the highest service levels. For example, where a safety stock of 2000 units is needed to achieve a service level of 90%, 4000 units might be needed to raise the service level to 99%.

There are many ways of estimating the safety stock required to achieve specific service levels. The more precise methods require historical data on consumption patterns, which is often not available. The simplest approach is to simply establish arbitrary levels and to then adjust them based on lead times and experience with the different types of drugs. Safety stocks should increase with the lead time, since there is a greater risk of stockouts with longer lead times. To maintain a constant service level, however, the safety stock increase need not be quite as great for each increase in lead time. A reasonable starting place might be the following:

Lead Time	Safety Stock
1 month	2 weeks' usage
2 months	4 weeks' usage
3 months	5 weeks' usage
4 months	6 weeks' usage
6 months	8 weeks' usage
8 months	9 weeks' usage
12 months	12 weeks' usage

"Two weeks' usage" for an item would be equivalent to the average number of units of that item consumed every two weeks.

For items such as cold remedies, smaller safety stocks might be maintained in order to use inventory funds preferentially for larger safety stocks of antibiotics and vaccines. Some specific guidelines for adjusting safety stocks according to drug type appear in Chapter VI.B.

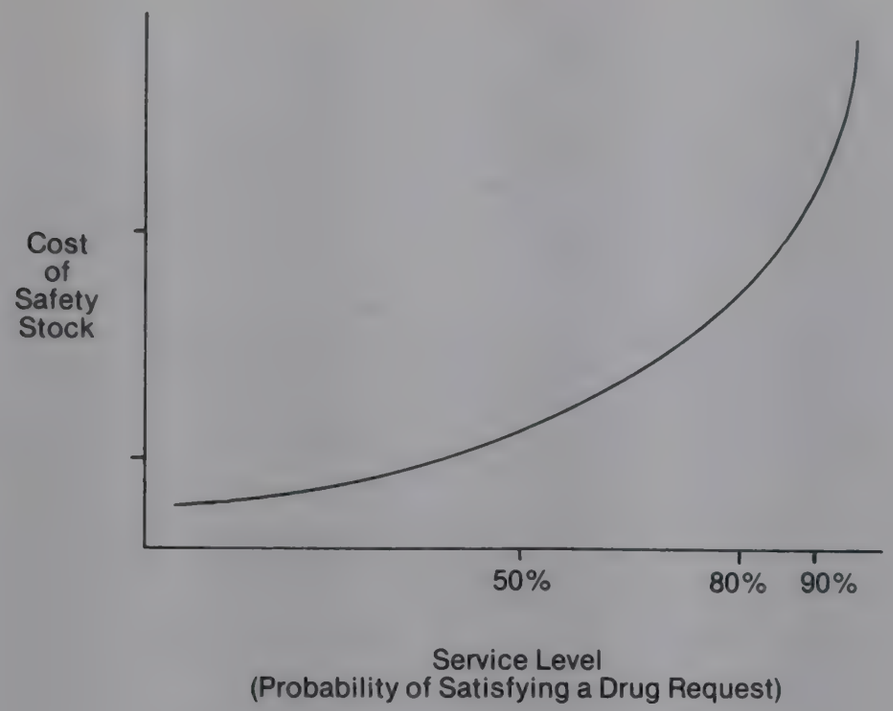
Carefully kept inventory records should indicate average stock levels, when stockouts occur, and how long they last. These records can then be used to adjust safety stocks upward or downward.

d. Types of Inventory Control Systems

Although numerous variations exist, inventory models are typically divided into two categories, periodic and perpetual systems. In the periodic inventory system -- also known as the fixed interval system, the T-system (time), or the economic order interval (EOI) system -- the inventory position is reviewed each time the order interval has passed and an order is placed for an amount equal to the difference between the current inventory

Figure IV.B.3.

Safety Stock Requirements to Maintain Service Levels



level and a predetermined maximum inventory level. The maximum inventory level consists of the safety stock plus a working stock equal to the average consumption during the order interval. Since the fixed interval model has no inherent mechanism for placing an earlier order when consumption is unusually high, the maximum level must be high enough to include a generous safety stock. A method for determining the optimal or economic order interval (EOI) is given in Appendix IV.B.1., although in practice order intervals are usually determined by some combination of administrative convenience, transport availability, storage capacity, and other such factors.

In the perpetual inventory system -- also known as the fixed quantity system, the Q-system (quantity), or the economic order quantity (EOQ) system -- the inventory level for each item is reviewed "continuously" (i.e., with each order, daily, or at least weekly), and whenever the stock falls below a predetermined reorder level an order is initiated. Each time an order is placed it is for a standard quantity, chosen as the optimal or economic order quantity (EOQ). Appendix IV.B.1. also provides one method of calculating this quantity. The reorder level is based on the average lead time; when the reorder level is reached there should be enough stock to last until the next order arrives. With a perpetual system, the reorder level will be reached more rapidly when consumption increases substantially and, therefore, additional stocks will automatically be ordered.

All of the inventory control methods described in subsequent sections of this chapter are based on either the periodic or the perpetual system. In general, perpetual systems are the most effective models to operate, but they require accurate, up-to-date inventory control records; fast, reliable

communications; and rapid, flexible transportation services. For most levels in public supply programs, variations of the periodic system are more feasible.

e. Stock Records

The basic management tool for inventory control activities is the stock record. In some settings this record is computerized, but manual stock records are completely adequate for all but the largest drug supply systems.

A stock record must exist for each item, the essential content of which is illustrated by the sample stock record card in Figure IV.B.4. The card records all transactions for an item, including receipts, issues, orders placed, orders received, and an indication of stock losses. In drug sales programs, unit costs are also included.

When a periodic system is in place, the maximum stock level is used to determine the order quantity at each review period. When a perpetual system is used, the reorder point indicates whether an order should be placed, and, if so, the order quantity indicates how much should be ordered. Orders are initiated by means of a Stock Replenishment Request (see Appendix IV.D.1. in Chapter IV.D.), which is submitted to the Procurement Unit.

There are several systems which have been used for keeping manual stock records. The common methods are:

(1) As file cards, stored vertically one behind another in alphabetical or numerical order in a card file or drawer;

(2) As file cards in a visible-edge record tray, with names and stock numbers on the lower edge and these edges overlapped to provide an index ("Kardex" system);

(3) As ledger sheets in a special loose-leaf notebook with the lower edges overlapped to provide a visible index ("Kalamazoo" system);

(4) Vertically in grooves with the edges staggered sideways at the right to provide a visible index (the "Vistem" system).

Since the stock record forms the basis for important procurement decisions, the stock clerks responsible for maintaining these records should be carefully chosen, well-trained, and closely supervised. Improperly kept stock records can seriously undercut the reliability of routine drug supply.

Stock record cards and stock ledgers can be designed in numerous ways, depending on the information needs of the individual supply system. The sample form in Figure IV.B.4. is designed for use in either a perpetual or a periodic system. Since proper use of such records is essential for dependable drug supply, the items on the form will be briefly described. Figure IV.B.6. describes the methods for calculating several of the reference numbers which appear on the stock record.

Figure IV.B.4.

Sample Stock Record Card

Front

STOCK RECORD CARD

MINISTRY OF HEALTH

Department of Medical Supply

Description:__________

Stock No.:__________

Unit of Issue:__________

Bin Location:__________

Alternatives:__________

Estimated Monthly Consumption: __________

Reorder Level:__________

Order Quantity:__________

Maximum Level:__________

Review Period:__________

Safety Stock:__________

Date	Document Number	Issued to/ Rec'd from	Received	Issued	Balance	Initial	Date	Document Number	Issued to/ Rec'd from	Received	Issued	Balance	Initial

Back

Order No.	Dated	Supplier	Quantity On Order	Arrival Date	Receiving Report No.	Amount Received	Short or Damaged	Usable Stock	Expiration Date

Description and Stock No. -- There should be a separate stock record for each item in the inventory. These records are identified both descriptively (e.g., Aspirin tabs., 325 mg.) and by the stock number. The stock numbers should follow a logical sequence based on therapeutic categories (Chapter II.A.), the order of products on the shelf, which may be the same as the therapeutic categories, or some other system.

Unit of Issue -- A standard pack size should be set for stock-keeping purposes; for example, 500-tablet jars of aspirin. When suppliers are allowed to provide drugs in non-standard sizes, it creates a great deal of confusion for inventory control and warehouse staff.

Bin Location -- For stock records kept at the medical warehouse, the bin location indicates where the product is actually stored.

Alternatives -- Where alternative pack sizes or similar drugs are available for issue when a specific item is out of stock, indicating the alternatives on the stock record card helps the warehouse staff to make a substitution. Substitutions should be approved by the chief storekeeper, who should be a pharmacist or have substantial experience with pharmaceuticals.

Estimated Monthly Consumption -- This may be an average figure from the previous year, or a number which is updated every few months based on recent consumption. Some stock control records are made with a set of summary boxes at the bottom of the page in which the actual consumption for each of the previous 12 to 24 months is totalled.

Reorder Point -- In perpetual inventory systems, including optional replenishment systems, management sets a stock level, below which an order for new stock must be initiated. In this system, the inventory control clerks check the balance (plus stock on order) against the reorder level each time a drug issue is made. As soon as the total of the balance plus stock on order falls below the reorder level, an order is filed.

Order Quantity -- For perpetual inventory systems there is also a set order quantity. Each time an order is placed, it is for this predetermined order quantity. If consumption is increasing rapidly and an item is being ordered too frequently, then the order quantity is adjusted upward.

Maximum Level -- In periodic inventory systems, a maximum stock level is set by management to help determine the order quantity each time an order is placed.

Review Period -- For periodic inventory control, management establishes the frequency with which stock levels are reviewed and orders initiated. With annual purchasing, this period is twelve months. Two, three, four, or six month review periods are also used.

Safety Stock -- Generally, the reorder level or maximum stock level is set to include the safety stock. Nevertheless, it is useful to indicate how much safety stock has been included in these calculations. Sometimes, the safety stock is kept behind a line on the shelf or in a separate location. If the balance is continually falling below the safety stock level, then a higher safety stock might be needed.

Receipt and Issue Information

Each time stock is received into the inventory or issued, the transaction must be recorded. This provides a record of stock movement and a running stock balance, needed for ordering purposes.

Document No. -- When a drug is issued there should be a numbered requisition form or similar document on which the amount requested is indicated. Necessary approval signatures should also be on this form. When drugs are received, the reference number to the receiving report should be entered here.

Issued to/Received from -- To maintain a trail of accountability for drug supplies, the name of the individual and facility to which stock is issued should be recorded. For receipts, the name of the supplier or shipper should be entered.

Received, Issued, Balance -- These columns are used just the way a checkbook is used. Quantities received are entered in the appropriate column and added to the previous balance to obtain the new balance. Quantities issued are entered in the issued column and subtracted from the previous balance to obtain the current balance. It is the current balance plus the quantity on order which is compared with the reorder level in a perpetual system.

Initials -- Again, for the purpose of maintaining a trail of accountability for drug supply, the stock clerk who posts a drug receipt or issue must initial the transaction. Later, if questions arise regarding a specific transaction, the responsible individual can be identified.

Order Information

On the reverse side of the stock record is information about outstanding orders. Whenever a supply contract is initiated, the order number, date of the order, supplier, and quantity on order should be listed. When the order arrives, it should be posted on this form with information regarding the amount received, the amount short or damaged (important for insurance purposes) and the amount of usable stock.

Keeping the amount on order up to date is important, since this quantity must be considered in determining when to place a new order or how much to order. The amount of usable stock which arrives in a shipment must be known in order to add this to the balance on the front side of the record. "Receipts" should include only the usable stock.

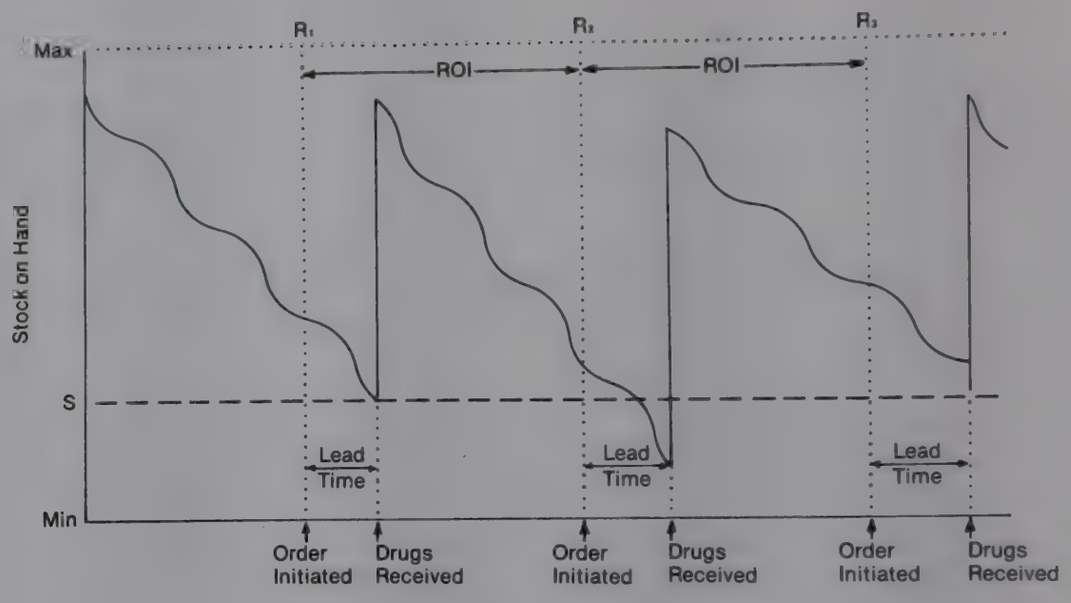
2. INVENTORY CONTROL AND PURCHASING AT THE CENTRAL LEVEL

There are four distinct types of inventory control systems which can be used at the central level (see Figures IV.B.5. and IV.B.6.). They are described here in terms of the advantages and disadvantages of each; a short comparative section follows the descriptions.

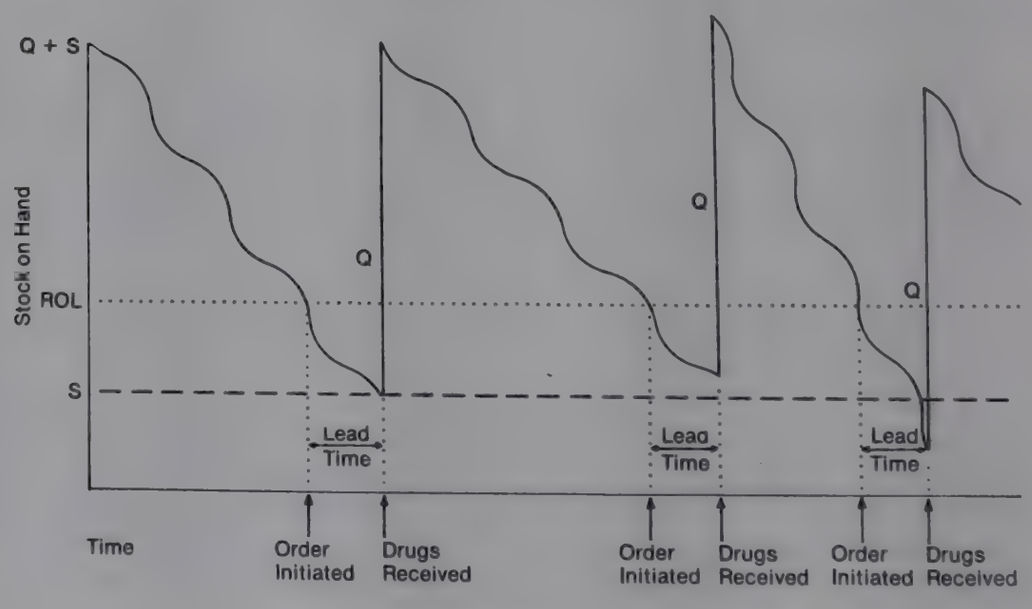
Figure IV.B.5.

Purchasing Patterns

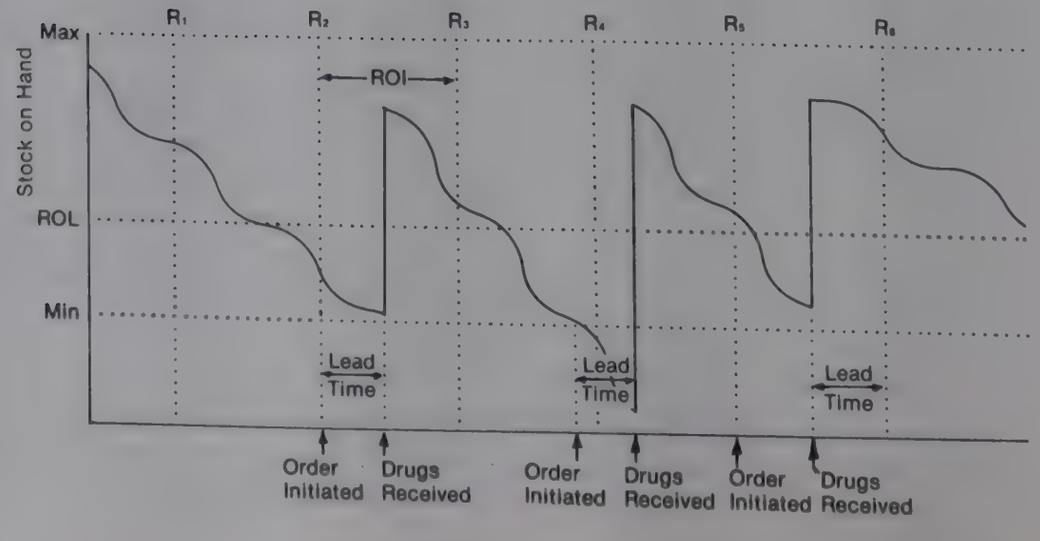
Periodic Purchasing



Perpetual Purchasing



Modified Optional Replenishment



Time in Months

Figure IV.B.6.

Technical Description of Purchasing Patterns

KEY TO SYMBOLS AND TERMS

D = Demand per unit time. Usually the average number of units issued per month.
LT = Lead Time. Time (usually in months) between initiation of an order and receipt of drugs. This is determined from experience and may be six to twenty-four months.
MAX = Maximum inventory position.
MIN = Minimum acceptable stock level.
Q = Order quantity, in units of stock.
R = Review point, the time at which stock levels are reviewed and decisions about orders are made.
ROL = Reorder level, the stock level at which an order is initiated in a perpetual inventory system.
ROI = Reorder interval, the time between review points ($R_2 - R_1$) in a periodic inventory system.
S = Safety stock.
TIP = Total inventory position, equal to the sum of stock-on-hand plus stock-on-order (minus back-orders if there are any).

PERIODIC PURCHASING

ROI is established by management. Setting the reorder interval determines the schedule for procurement activities. For annual purchasing the ROI is 12 months; for other scheduled purchasing it may be 3, 4, or 6 months.

S is also established by management. The longer the ROI, the lower the safety stock should be.

MAX is derived once the ROI is set from the lead time, reorder interval, safety stock, and average demand:

$$MAX = S + (ROI \times D) + (LT \times D)$$

Q is different for each order, depending on the TIP (stock-on-hand plus undelivered stock-on-order) at the time of review (R):

$$Q = MAX - TIP$$

PERPETUAL PURCHASING

Q is established by management. Each time an order is placed it is for the same standard quantity, Q. Setting Q is the main management decision which determines the other characteristics of a perpetual purchasing system. Q is usually set to equal 2 to 6 months supply, depending on how frequently management wishes to initiate orders.

S is also established by management. The safety stock can be smaller than in a periodic system.

ROL is determined by the lead time (LT) and the demand (D). Review of stock levels occurs each time an issue is posted on the stock record, or at least weekly. When the ROL level is reached, an order is initiated for the quantity, Q:

$$ROL = (LD \times D) + S$$

MODIFIED OPTIONAL REPLENISHMENT

ROI is established by management as the basic time interval for review of stock levels and initiation of orders.

ROL is also established by management to help prevent placement of small orders. The ROL is low enough to assure that a large order will be placed when the ROL is reached. At each review point (R), an order will not be initiated unless the stock-on-hand is below the ROL.

MIN is a minimum stock level set by management to prevent stockouts. Although there is a formal review period (ROI), stock levels are also reviewed less formally on a continuous basis. If stock levels are above the ROL at a formal review, but the stock-on-hand drops to below the MIN before the next review period, then an order is initiated.

MAX is established by management to help set order quantities. Although there is no safety stock as such, a safety stock quantity can be set for the purposes of determining MAX:

$$MAX = S + (ROI \times D) + (LT \times D)$$

Q is variable, depending upon the TIP (stock-on-hand plus undelivered stock-on-order) at the time of review:

$$Q = MAX - TIP$$

Two of the methods are periodic inventory systems: annual purchasing, and periodic or scheduled purchasing with review periods less than six months. The third method bases purchasing on a classic perpetual inventory model. The fourth model, modified optional replenishment, is based on a combination of periodic and perpetual inventory systems.

Figure IV.B.5. diagrams the purchasing methods and a technical summary of each system appears in Figure IV.B.6.

a. Annual Purchasing

Procuring drugs through a single major annual purchase is a common, if not the most common, pattern used by ministries of health in the countries we have studied. Although annual purchasing is in essence a periodic system with a review period of one year, there are enough distinctive features to warrant a separate discussion.

Under this system, drug requirements are determined once annually and contracts are awarded to suppliers for one year's expected drug consumption. Countries using this system generally have a mechanism for placing supplemental orders throughout the remainder of the year, should the need develop.

Method -- The inventory levels and order quantities for an annual purchasing system are determined by several factors (refer to Figure IV.B.5.). Since the central medical store is dependent upon a single large delivery or a small number of split deliveries and since there are many opportunities for delay in the processing of an order or shipment of goods, a large safety stock should be established.

In a stable program which is not growing appreciably, a maximum stock level (MAX) is set which is equal to the safety stock plus the average annual consumption plus the consumption during the lead time period. Then the order quantity is simply MAX minus total inventory position.

Most programs have not reached a steady state, however, and growth can be expected. In such instances, the order quantities can be determined from the projected demand for the coming year (see Chapter II.B. for estimation methods). The projected demand is then increased to supplement expected deficiencies in the safety stock at the time the supplies arrive, or reduced if excess working stock is expected at the time the supplies arrive.

Advantages -- The popularity of the single annual purchase is attributable to several factors:

(1) Accounting policies in some countries effectively require that funds be committed and expended within the same fiscal year. Procurement offices must initiate orders early in the year to assure that drugs arrive before the end of the fiscal year.

(2) When purchasing is done on the basis of estimated requirements submitted by a large number of separate health facilities, estimates are more readily collated to obtain the total purchase requirements if they are collected only once a year.

(3) A single annual purchase facilitates the comparison of estimated drug needs with available funds. From past price information and present estimates of quantities needed, a projection of procurement cost can be made and from this, adjustments in drug orders or funding can be made.

(4) A single large purchase is a convenient way to stock a drug supply system at its inception and annual purchasing may remain the pattern simply because no one looks beyond the idea of one large purchase.

Disadvantages -- Despite these attractive features, there are several significant drawbacks to annual purchasing:

(1) An uneven workload results. The staff with purchasing expertise are overwhelmed during the first part of the fiscal year by the need to initiate orders and negotiate purchase contracts. During the second part of the year these individuals are less active, while the port-clearing and warehouse staff are seriously overburdened.

(2) A large sum of money and, in many countries, foreign exchange allocation is required within a very short period. This can create difficulties in completing payment and clearing the goods from the port.

(3) Stocking the central warehouse when there is one large purchase a year requires more storage space and entails higher inventory holding costs than more frequent purchasing.

(4) Where a significant proportion of the suppliers are local agents and producers, annual purchasing can lead to collusion among bidders ("price fixing"). The reason for this is simple; if a company bids low and wins on too many items its capacity will be over-committed and it must either renege on some items, thereby jeopardizing its standing with the government, or subcontract some items, which is likely to cost more than the bid price. Conversely, if a supplier loses on too many items, it risks going out of business.

(5) Annual purchasing does not adjust well to changes in consumption patterns compared to systems where purchasing is more frequent. It is difficult for an annual system not to err, either by buying in excess or by buying quantities which prove to be inadequate.

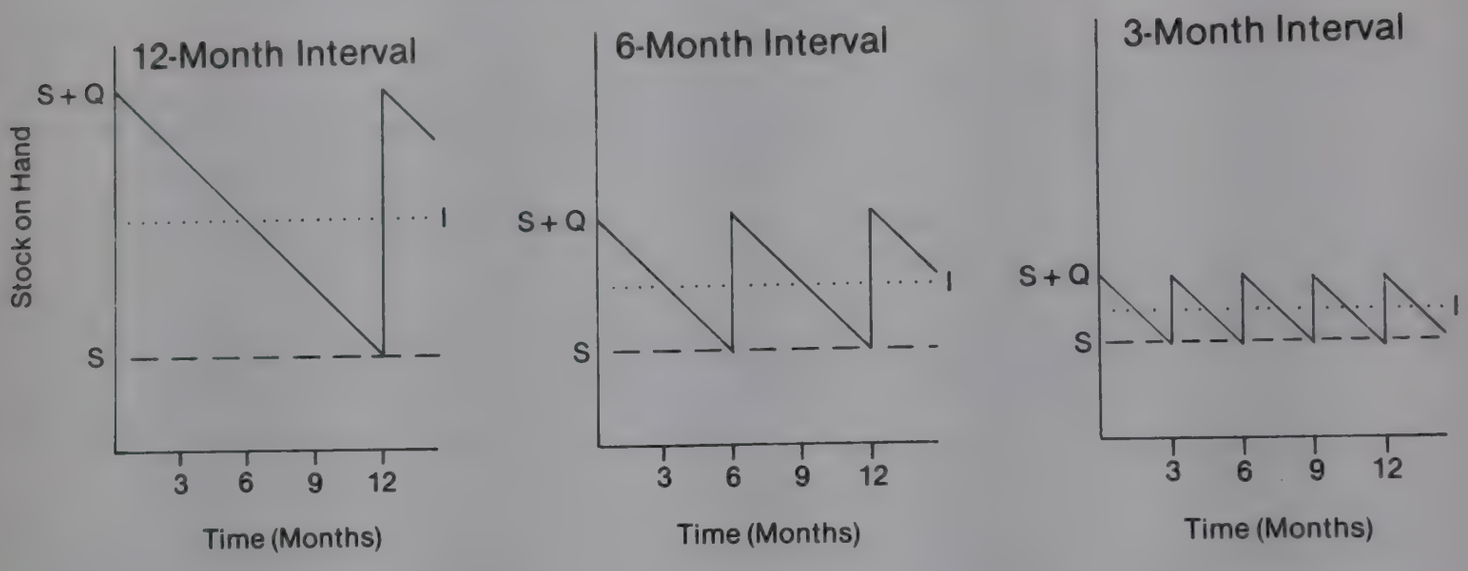
Comment -- Annual purchasing is a reasonable system to use in new or small programs. In most cases, however, procurement units will find other methods to be more efficient and more economical, as programs expand and more experience is gained with procurement activities.

b. Scheduled Purchasing

The term "scheduled purchasing" is used here to indicate any periodic inventory system in which the reorder interval is less than one year. In areas where there is ready access to supply sources and lead times are only a few months, reorder intervals of one, two, or three months are reasonable. However, for primary health care programs in most countries, three months

Figure IV.B.7.

Impact of Order Interval on Average Inventory



Key: I = Average Inventory Q = Order Quantity S = Safety Stock

would be the minimum feasible reorder interval and four to six months might be more reasonable.

Method -- Scheduled purchasing with a review period of three to six months can operate in much the same way as annual purchasing. The average working stock is smaller, since it is replenished more often with more frequent deliveries. If purchasing is done every six months instead of every twelve, the average working stock is reduced by one-half, as illustrated in Figure IV.B.7.

Determination of order quantities involves the same process as that for annual purchasing. For programs experiencing rapid growth, the increased order frequency allows purchasing patterns to more closely parallel program expansion. When applying estimates of future demand to current order quantities, the length of the lead time must be kept in mind. For example, with a six month review period and a twelve month lead time, estimates made in the fall of 1982 for tenders to be awarded in January 1983 should be for expected consumption between January and June 1984. Failure to incorporate lead time considerations into quantity estimates for rapidly growing programs will invariably lead to stockouts.

Country Study IV.B.1. describes a scheduled purchasing system in Papua New Guinea termed "regulated indenting". Under this system drugs are placed into three categories according to their usage pattern and, in some cases, pharmaceutical characteristics. Depending on the category, supply contracts are negotiated once, twice, or three times a year.

Advantages -- The major advantages of scheduled purchasing are that:

(1) The work load for all personnel is distributed somewhat more evenly throughout the year.

Country Study IV.B.1.

Regulated Indenting in Papua New Guinea

Papua New Guinea (PNG) is, in essence, an island country, dependent to a large extent upon air and sea transportation, rather than land transportation. As a result, the government Pharmaceutical Services Section has established central warehouses in five port cities. Eighty percent of drugs are shipped directly to these five ports, with only 20% shipped to the main port for subsequent redistribution. Virtually all purchasing is done on tenders through the PNG Office in Sydney, Australia.

Since the requirements of all five stores must be collated to determine order quantities and since procurement is done at a distance, a continuous inventory with perpetual purchasing would not be feasible. In order to spread evenly the workload of ordering and receiving and to minimize stock-holding costs, a system of Regulated Indenting was initiated. This system divides all items into lists, depending on whether the item is to be purchased once (List I), twice (List II), or three times (List III) per year:

List	Periods Covered	Item Categories	Examples
I Yearly Purchase (76 Items)	January-December	• Essential items • Highest volume items	• Ampicillin • Chloroquine • Aspirin • IV fluids
II Twice Yearly Purchase (142 Items)	January-June July-December	• Intermediate use items • Dangerous drugs • Drugs for epidemics (variable consumption)	• Dextrose-electrolyte tablets • Folic acid tablets • Asthma medications
III Thrice Yearly Purchase (249 Items)	August-November December-March April-July	• Highly variable consumption • Short shelf-life • Many direct purchase items	• Insulin • Most vaccines • Toxins, anti-toxins • Cloxacillin, Kanamycin

List I items are the highest volume items, for which considerable savings are achieved by bulk buying. The total value of these items is such that the PNG Office requires approval from the Central Tender Board in Port Moresby. As a result, the lead time is slightly longer. Savings are achieved by bulk purchasing contracts, even though shipments are often divided through the year into two or three deliveries. List II items tend to be cheaper per unit, so that bulk rates are not as critical. For some of these items, suppliers compete keenly and the biannual tendering appears to heighten their competition. The majority of items fall into List III, which are the items with high unit costs, highly variable consumption, and short shelf-lives.

The collated estimates from the five stores are used to raise indents which are then forwarded to the PNG Office. This Office handles the selection of suppliers, the signing of contracts, and the monitoring of suppliers to assure delivery. The Office prefers to deal with a "closed court" of, at most, 150 pharmaceutical suppliers; hence, when a new supplier approaches the Office with an offer, the Office gathers as much information about the firm as possible before awarding it a contract.

Direct purchases are made by the Office for items less than U.S.$3,500 and for selected items such as single source drugs and the few drugs which, for quality reasons, are bought only by brand name.

Competitive tenders are announced by mailings to potential suppliers and by publication in the Sydney Morning Herald, a paper with an international circulation. For each product or product category (e.g., the penicillins), a list of acceptable and interested suppliers is maintained by the Office. These suppliers -- usually 5-10, but up to 40 in number -- are certain to receive the tender notice by mail. Occasionally, a tender will not attract a single offer. The Office then seeks out suppliers and solicits an offer. Reputable firms are frequently helpful in guiding the Office to sources of products which they do not make themselves.

For purchases of more than about U.S.$120,000, the Central Tender Board in PNG must also approve the selection of supplier.

(2) Inventory costs are substantially reduced compared to annual purchasing.

(3) Supply needs for high usage or variable usage items can be reconsidered more frequently, which reduces the need for costly emergency shipments.

(4) Even though there are more procurement periods during the year, there are still few enough that estimated expenditures can be compared with remaining budget allocations to determine whether adjusts in purchase quantities must be made.

Disadvantages -- The major difficulty with scheduled purchasing is that it may complicate accounting and reporting procedures, since most procurement cycles will not start and end in the same fiscal year.

It is important to recognize that there is nothing wrong with a reorder interval which is shorter than the lead time. Although in most systems an order for one item is received before another order is placed, in systems such as in Papua New Guinea some items may have a lead time of twelve months and a reorder interval of three months. Provided lead times can be reasonably well estimated, adjustments in order can readily be made for anticipated deliveries.

As in the case of annual purchasing, scheduled purchasing risks dangerous shortages or stockouts, since stock levels are formally reviewed only at three to six month intervals. This pitfall can be avoided if inventories are more frequently reviewed on an informal basis, possibly by having the chief storekeeper walk through the medical stores once every two weeks to do a "visual stock-take".

Comment -- Scheduled purchasing is used successfully in many large programs. With annual purchasing and scheduled purchasing, though to a lesser extent, there is always the possibility that the inventory level will reach a dangerously low point as a result of a sudden change in consumption, for example, due to an epidemic. It is important, therefore, to include some form of warning system or emergency stock level in any periodic inventory system.

c. Perpetual Purchasing

Perpetual purchasing patterns are followed in Malaysia, Costa Rica (see Country Study III.B.1. in Chapter III. B.), and in many other public supply programs.

Method -- In this system, the inventory level is reviewed on a regular basis (usually with each transaction, but at least weekly), and whenever the stock level falls below a predetermined point -- the reorder level (ROL) -- an order is initiated. Each time an order is placed, it is for a standard quantity, chosen as the economic order quantity. The reorder level is based on the safety stock, the average lead time, and the average consumption. There should be enough working stock when the reorder level is reached to last until the next order arrives.

Although the economic order quantity can be calculated (see Appendix IV.B.1.), it is frequently established in public drug supply programs to represent three to six months' consumption. If the consumption of an item is increasing rapidly and orders are being placed too frequently, then the order quantity is increased.

Advantages -- The chief advantage of this system is that it allows rapid response to sudden increases in consumption, since the inventory position is reviewed almost continuously. The operation of a perpetual inventory system requires accurate inventory control information and frequent review of inventory records. It is not surprising that the programs which are successfully using this system have well organized information systems and reliable consumption data.

The perpetual system provides potentially the most even distribution of the workload throughout the year, making it easier for specialized procurement staff to work continuously in their area of expertise. Unfortunately, the workload is not completely predictable and occasionally may increase markedly for a brief time.

Inventory control and review of reorder levels in a perpetual system is greatly facilitated by the availability of computers for electronic data processing (EDP).

Disadvantages -- In spite of the advantages of a perpetual purchasing system, there are several disadvantages to its use in typical government supply systems:

(1) In programs where drug supply contracts are negotiated centrally based on estimated needs from multiple regional stores (as in Papua New Guinea) or multiple health districts, it would be extremely difficult to coordinate the review of stock levels for each item at the various facilities.

(2) With this system it is somewhat more difficult to plan and anticipate drug needs and thus to control drug expenditures at the central level. Under scheduled purchasing, on the other hand, need can be estimated in advance, compared with available funds, and appropriate adjustments made in drug selections, quantities, or funding. This difficulty in cost accounting under perpetual purchasing need not be a problem if the central purchasing office is serving simply as an intermediary agent; it, then, in essence, sells the drugs to other health facilities.

(3) Depending on the review period, perpetual purchasing systems generate orders on a daily, weekly, or sometimes monthly basis. Where communication is difficult and advertisement of tenders is a lengthy, involved process, such frequent ordering may be quite difficult.

Comment -- Perpetual purchasing is probably best instituted in a setting where a well functioning information system exists, where communication with suppliers is prompt and accurate, and where the program desires tight inventory control and rapid response to changes in consumption.

d. Modified Optional Replenishment

A variation of the fixed order interval system is the optional replenishment system (Figure IV.B.5.) in which there is a reorder level (ROL) as well as a reorder interval (ROI) and a maximum stock level (MAX). At the normal review period, if the stock of an item is being consumed particularly slowly and the inventory is above the ROL, then no order is made. This method tends to protect the system from habitual overstocking, but it risks more frequent shortages. To prevent this, the modified optional replenishment system adds a minimum stock level (MIN), thus providing a second control limit. The ROL is used at the formal review periods and the MIN is used between formal review periods, in case the inventory position reaches a dangerously low level.

A modified optional replenishment system has been in use for the last six years by the State Pharmaceuticals Corporation of Sri Lanka for purchasing a range of about 1000 drugs.

e. Choosing a Procurement Pattern

As in other aspects of drug supply, the selection of an inventory control and purchasing system for the central level must reflect local conditions and incorporate local requirements. None of the four systems just described can be recommended as the best system for all programs. With this in mind, the following summary remarks are offered:

- Annual purchasing is the simplest to administer, although it does entail markedly uneven workloads. Nevertheless, it is a useful system for small, new programs.

- Annual purchasing requires extremely high safety stocks and working stock. For this reason, it should be avoided as a permanent system.

- Scheduled purchasing at intervals of three to six months offers much of the administrative simplicity of annual purchasing, but with smaller inventories and a more even workload.

- When central procurement is used and goods are shipped directly to regional warehouses, a periodic inventory system (annual or scheduled purchasing) is preferable.

- A perpetual inventory system responds fastest, and an annual purchasing system responds slowest, to changes in demand.

- Perpetual purchasing and modified optional replenishment systems require great administrative skill and experience, but when managed properly can be the least costly.

- Balancing drug orders against available funds is easiest with annual purchasing and the most difficult with perpetual or modified optional replenishment systems.

- Some procurement patterns may be incompatible with government accounting requirements. Where such requirements prevent the adoption of an other-

wise superior system, efforts should be made to obtain an exemption from the specific requirements.

It should be apparent from this summary that different inventory control systems may be advantageous at different stages in a program's growth. In light of this, it may be wise to consider changes in the inventory system as a program evolves.

3. INVENTORY CONTROL AT THE REGIONAL AND DISTRICT LEVEL

Inventory control at the regional and district level is generally determined by transportation and storage considerations. As a result, the most common system is a periodic inventory with a review period and delivery interval of two, three, or four months.

At each review period, the Chief Storekeeper, or his equivalent, reviews the stock records for each item and, based on the current inventory position and recent consumption patterns, estimates drug requirements for the next supply period. These requirements are recorded on an officical requisition and transmitted to the central medical store. Chapter IV.D. describes the remainder of this process and contains samples of the documents used.

The frequency of requisitions and subsequent deliveries depends on the storage capacity of the regional and district medical stores and the number and size of vehicles. Frequent deliveries reduce the amount of inventory required and, therefore, the amount of storage space needed (Figure IV.B.7.). More vehicles or other means of transport are needed, however.

In some programs, there is no real requisitioning process. Instead, standard quantities are delivered every two to four months. This is the case where individual regional or district stores are asked to estimate their requirements for one year in advance. After any necessary adjustments for funding limitations are made, these facilities receive one-sixth of their estimated needs every two months, one-fourth every three months, or one-third every four months. Although this system encourages facilities to estimate their needs well in advance and provides a means for reconciling estimated needs and available funds, it frequently results in shortages of certain items and accumulating surpluses of others.

The classical periodic inventory model does not contain adjustments for seasonal variations in demand. However, regional and district medical stores must anticipate usual seasonal fluctuations in drug consumption and adjust the quantities on the requisitions to reflect these variations in drug requests. Regional and district medical stores at risk of being cut off during the rainy season should be allowed to accumulate sufficient supplies before the rainy season begins to last until roadways are again open.

Maintenance of a stock record is as important at the regional and district level as it is at the central level. File card or ledger formats are equally acceptable. These records are the basic tool for determining order quantities and for generating consumption reports.

Figure IV.B.8.
Sample Clinic/Pharmacy Stock Record Card

Front

CLINIC/PHARMACY STOCK RECORD CARD

Description:__________ **MINISTRY OF HEALTH** Reorder Level:__________
Stock No.:__________ Department of Medical Supply Order Quantity:__________
Unit of Issue:__________ Maximum Level:__________
Bin Location:__________ Estimated Monthly Review Period:__________
Alternatives:__________ Consumption:__________ Safety Stock:__________

Date	Document Number	Issued to/ Rec'd from	Received	Issued	Balance	Initial	Date	Document Number	Issued to/ Rec'd from	Received	Issued	Balance	Initial

Back

Date	Document Number	Issued to/ Rec'd from	Received	Issued	Balance	Initial	Date	Document Number	Issued to/ Rec'd from	Received	Issued	Balance	Initial

4. STOCK CONTROL AT CLINICAL FACILITIES

Stock control at hospital pharmacies, health centers, aid posts, dispensaries, and other clinical facilities differs in several respects from that at major medical stores. At clinical facilities there is rarely even a single individual for whom stock control is a full-time responsibility. Pharmacists and dispensers spend most of their time filling outpatient prescriptions and resupplying hospital wards. Physicians, medical auxiliaries, nurse auxiliaries, village health workers, and other practitioners are given the responsibility for managing drug stocks for their facilities, but seldom have sufficient time to devote to stock-keeping activities. Moreover, clerks and often health workers who handle drug supplies are functionally illiterate, making the use of standard stock control forms impossible.

As a result of these factors, inventory control procedures must be individualized to suit the information needs and the staff capabilities at each category of health facility.

Major Health Facilities

Hospital pharmacies and large health centers should be expected to keep individual stock records using one of the file card or ledger systems described above (e.g., Figure IV.B.8.). These records can be somewhat simpler than those for central medical stores (e.g., Figure IV.B.4.), but entries should be just as conscientiously recorded. Requisitioning of supplies should be done using forms and procedures similar to those described in Chapter IV.D.

Peripheral Health Facilities

In general, stock control procedures at small health centers, dispensaries, and other clinical facilities should be supervised by a pharmacist or other stock control expert from the major health facility or area medical store from which drugs are received. Supervision and management of drug supply is greatly facilitated by standardization of stock control mechanisms, such that the same types of health facilities have the same inventory control procedures throughout the country.

Limited time, lack of interest, absent or inadequate supply training and supervision, and, frequently, low literacy rates combine to make supply management at peripheral facilities difficult. These factors also lead to the use of different inventory control procedures at many clinical facilities.

There are at least three stock control methods which have been successfully used at peripheral health facilities: the imprest system, the two-bin or double-shelf system, and visible inventory. These systems do not result in the filing of consumption records at the health facility in the way that standard stock records would. With these systems, consumption information for individual facilities must be derived from the issue records at the medical store which supplies the facility.

The remainder of this section will provide descriptions of each of the three techniques just mentioned.

a. Imprest System

With the imprest or "topping-off" system stocks are replenished up to a level called the imprest level at each review period; no running stock records are kept. The only stock control document is a preprinted sheet showing for each item its description, stock number, unit of issue, and imprest level. The sheets contain various additional columns, depending on whether a one-step, two-step, or three-step imprest system is used.

Imprest stock control is a form of periodic inventory, the order interval for which is determined by the delivery schedule. Whenever a delivery is due -- usually once a month or once every two months -- the responsible physician, nurse, medical auxiliary, or clerk looks at the store closet or walks around the storeroom with the imprest sheet and records the stock on hand. This sheet is then carried or sent to the issuing medical store. Supplies may be issued directly to the representative of the health facility who brings the imprest form or they may be brought to the health facility as part of a routine delivery schedule.

Imprest quantities for each item are initially estimated from available information on drug consumption and disease patterns. Over time these quantities are adjusted as needed, usually on a trial-and-error basis. Some new programs have successfully used population-based or service-based epidemiological estimates as described in Chapter II.B. to establish imprest levels.

Figure IV.B.9. provides samples of imprest sheets for one-step, two-step, and three-step systems. These sheets can easily be produced by mimeograph, photocopying, or, if necessary, by hand.

One-Step Version -- This adaptation requires the health worker simply to record in column 5 the number of units of stock on hand. The pharmacist or responsible storekeeper at the area medical store then takes the difference between the imprest level (column 4) and the stock on hand, to determine the stock required (column 6). Since the medical store may not be able to issue all that is required, column 7 records the amount actually issued.

Two-Step Version -- This version requires the health center to fill in the quantity requested (column 6) as well as the stock on hand (column 5). This allows the health center staff to use their experience to adjust quantities. The district medical store may revise this request if it is felt to be unreasonable in any way.

Three-Step Version -- Health center staff are requested to enter opening stock levels at the beginning of the two month supply period (column 5), which can usually be calculated from the previous imprest sheet, count the stock on hand (column 6), calculate the two month consumption (column 7 = 5 - 6), and make a specific request for supplies (column 8). This version obviously provides the most information and the most accurate means to predict future demand. However, it also requires the most time, motivation, and mathematical ability.

Imprest forms are usually kept in a chronological file and the three-step version provides a particularly clear record of consumption.

Figure IV.B.9.

Sample Imprest Forms

a. ONE-STEP VERSION

Ministry of Health
Department of Medical Supply
Two Month Imprest Order

Health Facility:_____ Submitted by (name):_____
Supply Period:_____to_____
Date Submitted:_____

				Requesting Facility	Area Medical Store Use Only	
Stock No. (1)	Description (2)	Unit of Issue (3)	Imprest Level (4)	Stock on Hand (5)	Stock Required (6)	Stock Issued (7)
1.12.1	Adrenalin Inj. 1:1000	amp.	5			
5.01.1	Aspirin Tabs 300 mg.	100	20			
8.04.1	Chloroquine Inj. 80mg/2ml	amp.	10			
8.04.2	Chloroquine Tabs	100	10			

b. TWO-STEP VERSION

Ministry of Health
Department of Medical Supply
Two Month Imprest Order

Health Facility:_____ Submitted by (name):_____
Supply Period:_____to_____
Date Submitted:_____

				Requesting Facility		Area Medical Store Use Only	
Stock No. (1)	Description (2)	Unit of Issue (3)	Imprest Level (4)	Stock on Hand (5)	Quantity Requested (6)	Stock Approved (7)	Stock Issued (8)
1.12.1	Adrenalin Inj. 1:1000	amp.	5				
5.01.1	Aspirin Tabs 300 mg.	100	20				
8.04.1	Chloroquine Inj. 80mg/2ml	amp.	10				
8.04.2	Chloroquine Tabs	100	10				

c. THREE-STEP VERSION

Ministry of Health
Department of Medical Supply
Two Month Imprest Order

Health Facility:_____ Submitted by (name):_____
Supply Period:_____
Date Submitted:_____to_____

				Requesting Facility				Area Medical Store Use Only	
Stock No. (1)	Description (2)	Unit of Issue (3)	Imprest Level (4)	Opening Stock Level (5)	Stock on Hand (6)	Two Month Consumption (7)	Quantity Requested (8)	Quantity Approved (9)	Stock Issued (10)
1.12.1	Adrenalin Inj. 1:1000	amp.	5						
5.01.1	Aspirin Tabs 300 mg.	100	20						
8.04.1	Chloroquine Inj. 80mg/2ml	amp.	10						
8.04.2	Chloroquine Tabs	100	10						

Variations -- Several variations on the above three imprest systems are possible. In some one-step systems the imprest number for each facility is kept in a record at the district medical store, but is not printed on the form. This allows the same form to be used for different types of institutions and it also allows some adjustments for individual facility size.

Adjustments for variations in drug usage can be built into the system, either by the health centers requesting greater quantities prior to high usage seasons or by the district medical store automatically adding extra stock at this time.

Finally, it is common to produce several categories of sheets, each one corresponding to a different type of health facility.

Comments -- An imprest system can contribute significantly to the consistency and reliability of supply at peripheral facilities. Several points are noteworthy:

- The list of imprest items can serve as a teaching reference for medical auxiliaries and other health workers to assure that therapeutics training and the drugs supplied coincide.

- The final decision regarding issue quantities is placed upon the most skilled person in the chain: the hospital or district medical store pharmacist or supervising storekeeper. The system provides this individual with a reasonable amount of information without burdening the field staff.

- Forms are adaptable to several levels of mathematical ability.

- Copies of the imprest forms can be bound by individual facility at the medical stores and serve as a consumption record for future planning.

- The imprest level should include a safety stock sufficient to prevent stockouts under normal conditions (provided the system has been sufficiently well-supplied and managed to assure drug availability).

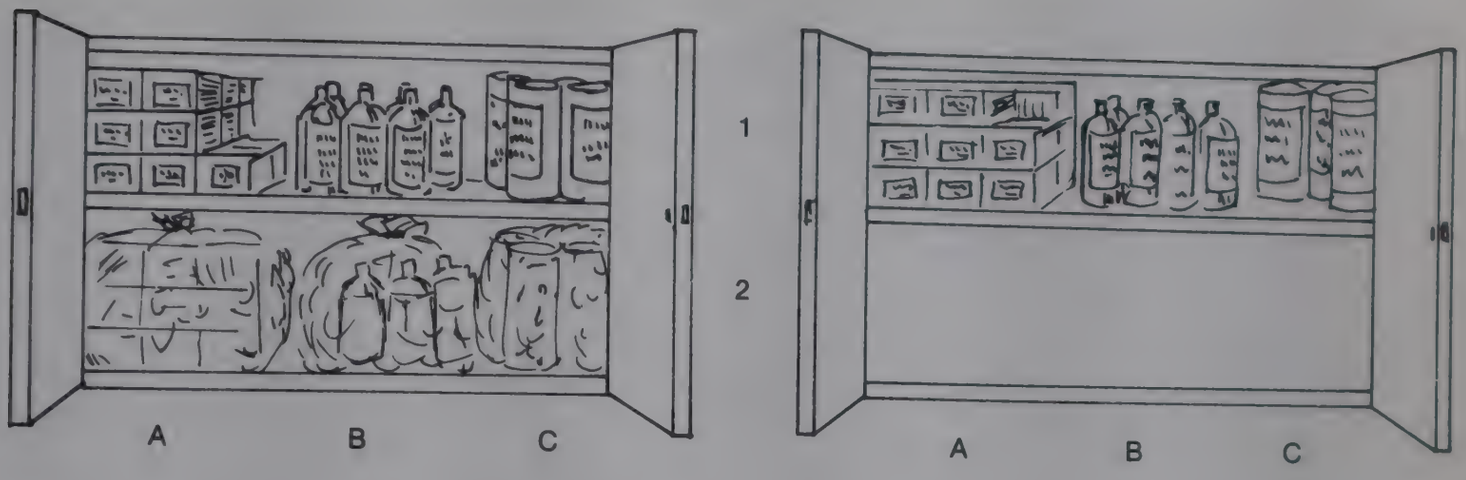
- Imprest levels can perpetuate chronic over-stocking of individual items or facilities and under-stocking of others. Staff from the local hospital or issuing medical store should make periodic supervisory visits if at all possible.

- Elementary as the system is in many ways, it is prone to degenerate into a zero-step system in which forms are returned simply with check marks in the stock-on-hand column for items which are needed. Adequate training of supply staff at the time the imprest system is introduced and regular supervision should help prevent this problem.

- The "unit of issue" frequently leads to confusion. A particularly vexing circumstance occurs when the issue unit is a bottle of 100 tablets, the imprest level is 5 (that is, 5 bottles of 100 each), but the current supply is in bottles of 250. Two bottles is 5 issue units! Confusion is reduced if drugs are supplied in standard course-of-therapy packaging, as described in Chapter V.B.

Figure IV.B.10.

Double-Shelf Inventory Control System



Adapted from McMahon, 1980.

Although the imprest system does not require a card file or stock ledger, some system of filing prescriptions or keeping a dispensing ledger is important as a part of the clinical record.

b. The Two-Bin or Double-Shelf System

Another no-paperwork system for stock control, the two-bin system, is a variant of the perpetual system. The stock of each item is physically separated into two bins -- the working bin and the reserve bin. When the working bin is empty, the health worker changes to the second bin and is alerted that new supplies are needed. The reserve bin should contain enough stock to cover the expected lead time and a small safety stock.

Although the two-bin system is a perpetual system, it can be adapted for use at a peripheral facility which receives deliveries only at scheduled intervals. A checklist of all items in stock can be used to indicate in advance the items for which the first bin is empty and, therefore, replacement is needed. The quantities in each bin could be established in such a way that each new delivery would be placed in the reserve bin and the remaining reserve stock moved to the working stock bin.

A modification of this system which works well for small health facilities is the double-shelf system (Figure IV.B.10.). When new stock arrives, it is divided into two parts, which are placed separately on two shelves. The stock placed on the bottom shelf is sealed in plastic bags or bound in some other way, and labeled "not to be used until new order is sent." When the drugs on the top shelf are finished, the health worker begins to use the remaining stock, and sends off a new order. This system works well only if the supply time is half the purchasing interval.

c. Visual Inventory Control

Visual inventory control is based on actually looking at the stock to determine when additional stock is needed. In this respect it is the most basic form of inventory control possible. Experienced pharmacists and supply clerks operating in the absence of a formal inventory system frequently become quite skilled at determining stock requirements by glancing at each of the items on the shelf.

A more structured form of visual inventory, similar to the two-bin system, relies on lines drawn on the stock shelves. The stock of each item is lined up systematically from the back of the shelf to the front. Drugs are issued from the front of the shelf. A line is drawn across the shelf to indicate the division between the working stock and the reserve. When the line is crossed drugs are dispensed from the reserve and this is an indication that the item should be reordered. Notations on the shelf can be used to specify order quantities. A second line dividing the rearmost stock can be used to separate an emergency stock which, when the working and reserve stocks are spent, should be used only for the most acute situations.

SUMMARY

The basic challenge of inventory management is balancing the benefits of keeping stock on hand against the costs of stock-holding.

Benefits of inventory are that it (1) protects against uncertainty in supply and demand, (2) permits bulk purchasing, (3) improves distribution efficiency and use of transportation, and (4) can be used to anticipate seasonal fluctuations in consumption.

Costs include the capital cost (inventory is like money in the bank) and storage costs (stock-keeping, deterioration, obsolescence, expiration, and pilferage).

Inventory consists of working stock and safety stock. Working stock is determined by the type of inventory control system. Safety stock is determined by management. Higher safety stock means greater expense, but fewer stockouts.

Stock records in the form of file cards or ledgers are necessary at all but the smallest facilities. Staff should be taught to use them and be supervised.

Inventory models are of two basic types:

Periodic -- stock levels reviewed at predetermined intervals and orders based on current stock level and an established maximum.

Perpetual -- stock levels constantly reviewed and orders placed only when stock falls below a predetermined level.

At the central level, purchasing and inventory control can follow one of four patterns:

(1) Annual purchasing -- a common, but potentially costly system;
(2) Scheduled purchasing -- periodic procurement at quarterly or semi-annual intervals; the system of choice for many programs;
(3) Perpetual purchasing -- based on a perpetual inventory; potentially the most economical, but also the most demanding of staff;
(4) Modified optional replenishment -- a complex system suited to large, established programs.

At regional and district levels and in major health facilities, periodic inventory control for scheduled deliveries is usually the most practical system.

At peripheral health facilities, less complex inventory control and requisition procedures are needed. Two options:

- Imprest System, using checklists of varying detail to reorder drugs, no permanent stock records kept;
- Two-Bin System, a form of visual inventory, using separate bins or shelves to indicate reorder points.

CHAPTER IV.B. REFERENCES

Attwood, P.R.: Planning a Distribution System. London: Gower Press Limited, 1971.

Ammer, D.C.: Purchasing and Materials Management for Health Care Institutions. Lexington, MA: D.C. Heath and Co., 1975.

Bailey, P.J.H.: Purchasing and Supply Management, 2nd Edition, New York: Chapman and Hall, 1969.

Bowersox, D.J.: Logistical Management. New York: Macmillan Publishing Co., Inc., 1974.

Davis, G.M. and Brown, S.W.: Logistics Management. Lexington, MA: D.C. Heath and Company, 1974.

Dias, V.: Introduction to Forecasting and Inventory Control Systems. State Pharmaceuticals Corporation Report 1. Colombo, Sri Lanka: National Institute of Management, 1975.

Greene, J.H.: Production and Inventory Control Handbook. New York: McGraw Hill Books Company, 1970.

Management Sciences for Health: A Logistics Handbook. Cambridge, MA: Management Sciences for Health, 1976.

McMahon, R. et al.: On Being in Charge - A Guide for Middle-Level Management in Primary Health Care. Geneva: World Health Organization, 1980.

United Nations: Supply Management: Towards Better Use of Equipment and Material Resources in Developing Countries. New York: United Nations Department of Economic and Social Affairs, ST/ESA/SER.E/16, 1978.

Appendix IV.B.1.

Determination of Economic Order Interval and Economic Order Quantity

The formulae listed below are based on the following definitions:

EOI = economic order interval (in months)
EOQ = economic order quantity (in units)
A = annual usage of an item in units
C = cost of placing and receiving an order (dollars per order)
P = purchase price per unit of each item (dollars per unit), including freight, discounts, etc.
I = inventory holding cost $\left(\frac{\text{percent per year}}{100}\right)$

1. Economic Order Interval

The economic order interval for procuring an individual item in a periodic inventory system is given by the formula:

$$EOI = \frac{288C}{API}$$

For example, if the ordering cost is $4.00, the annual usage is 600 units, the cost of each unit is $10.00, and the inventory holding cost is 30 percent, then the EOI would be 0.8 months or about 24 days:

$$EOI = \frac{288 \times \$4.00}{600 \times \$10.00 \times 0.30} = 0.8 \text{ months}$$

If orders are placed on the average every 24 days, then there will be 15 orders per year, the average size of which would be 600/15 = 40 units.

2. Economic Order Quantity

For a perpetual system, the economic order quantity for an individual item can be determined from the following formula:

$$EOQ = \frac{2AC}{PI}$$

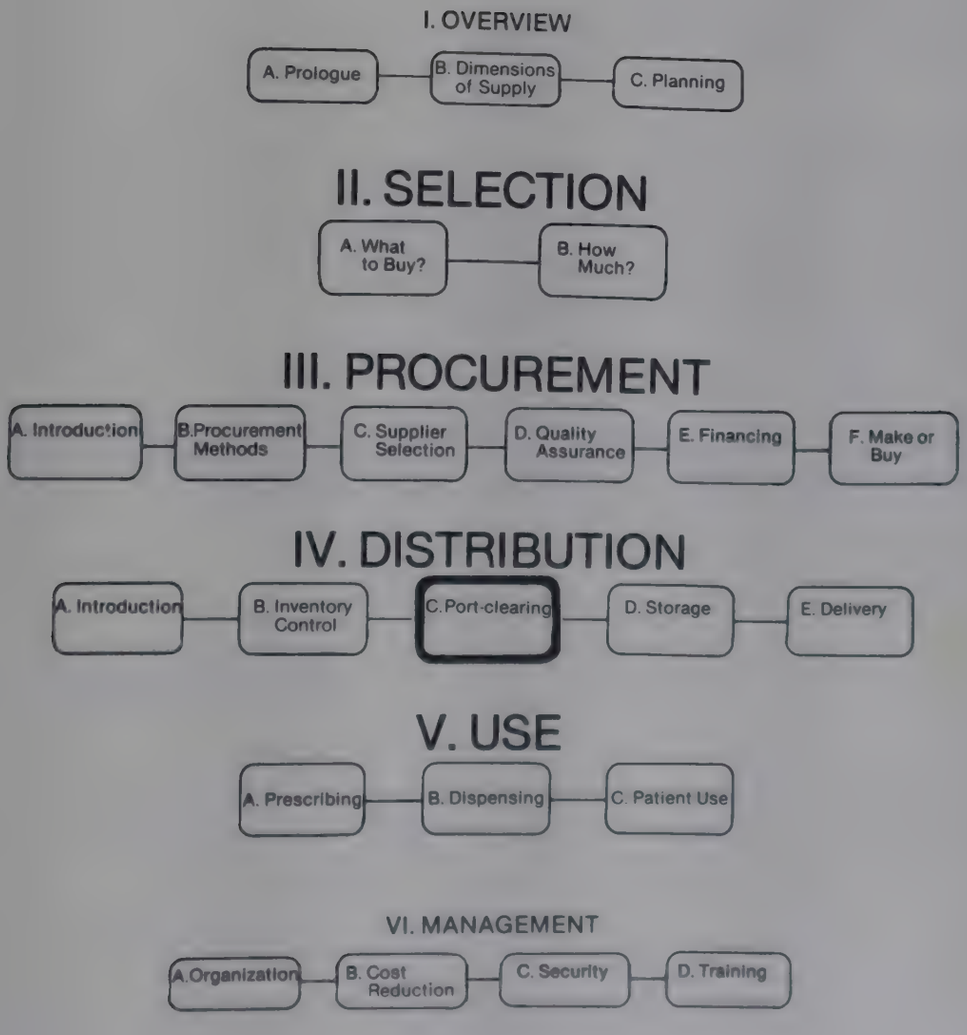
Using the same example as above, the EOQ would be:

$$EOQ = \frac{2 \times 600 \times \$4.00}{\$10.00 \times 0.30} = 40 \text{ units}$$

This value is the same as the average order quantity of 40 units calculated above from the economic order interval. This is as it should be for the same item.

Chapter IV.C.

Importation and Port-Clearing



	Page
1. THE PORT-CLEARING PROCESS	325
a. Identifying the Arrival of Shipments	325
b. Locating the Shipments	327
c. Documents Needed for Clearing	327
d. Delivery to Warehouse	329
2. EXPEDITING PORT-CLEARING	329
a. Use of an Activity Monitoring System	329
b. Acquiring Information Regarding Expected Consignments	329
c. Obtaining Necessary Documents	331
3. PRESSING INSURANCE CLAIMS	331
4. IMPACT OF GOVERNMENT CUSTOMS AND IMPORTATION REGULATIONS ON THE EFFICIENCY AND ECONOMY OF PORT-CLEARING	332
5. ORGANIZING AN IMPORT UNIT	333
SUMMARY	333
REFERENCES	334

Importation and Port-Clearing

In many countries the clearing of drug consignments from ports is a rather inefficient and time-consuming activity which leads to many losses. Unlike products which are non-perishable or indestructible, drug products are quite vulnerable to poor storage conditions and poor handling. They are also highly attractive items, making their theft much more likely than the theft of more mundane imports. Thus, there is a critical need to expedite the clearing of drugs from air, sea, and land ports.

Losses can be extensive and are often proportional to the delay in clearing goods from the port. Types of losses include:

- reduction of shelf life or, as in the case of vaccines, complete loss of potency of a pharmaceutical when it is kept in the port under improper storage conditions;
- increased pilferage resulting from damages to cartons caused by poor handling;
- demurrage fees owed to port authorities for delays in clearing;
- stockouts at storage and dispensing facilities when port-clearing delays lengthen the lead time, unless funds are invested to increase safety stocks;
- exacerbation of cash flow problems in programs operating a revolving drug fund; capital funds are tied up by port-clearing delays.

Obviously, the individuals responsible for port-clearing perform a vital function in the operation of a public supply program. Systems and procedures which can improve the efficiency of port-clearing are discussed in this chapter.

1. THE PORT-CLEARING PROCESS

Port-clearing consists of several successive activities, the most important of which are presented below.

a. Identifying the Arrival of Shipments

As soon as a consignment of drugs is shipped by the seller, it is the seller's responsibility to inform the buyer of such details as the name of the carrying vessel and its expected time of arrival at the buyer's port. This is often done by cable and followed by the seller dispatching to the buyer copies of all the documents mentioned in Figures IV.C.1. and IV.C.2. Once the buyer receives these documents he can contact the local agents of the carrying vessel to obtain information regarding its exact arrival date.

Figure IV. C. 1.

Processing of Import Documents

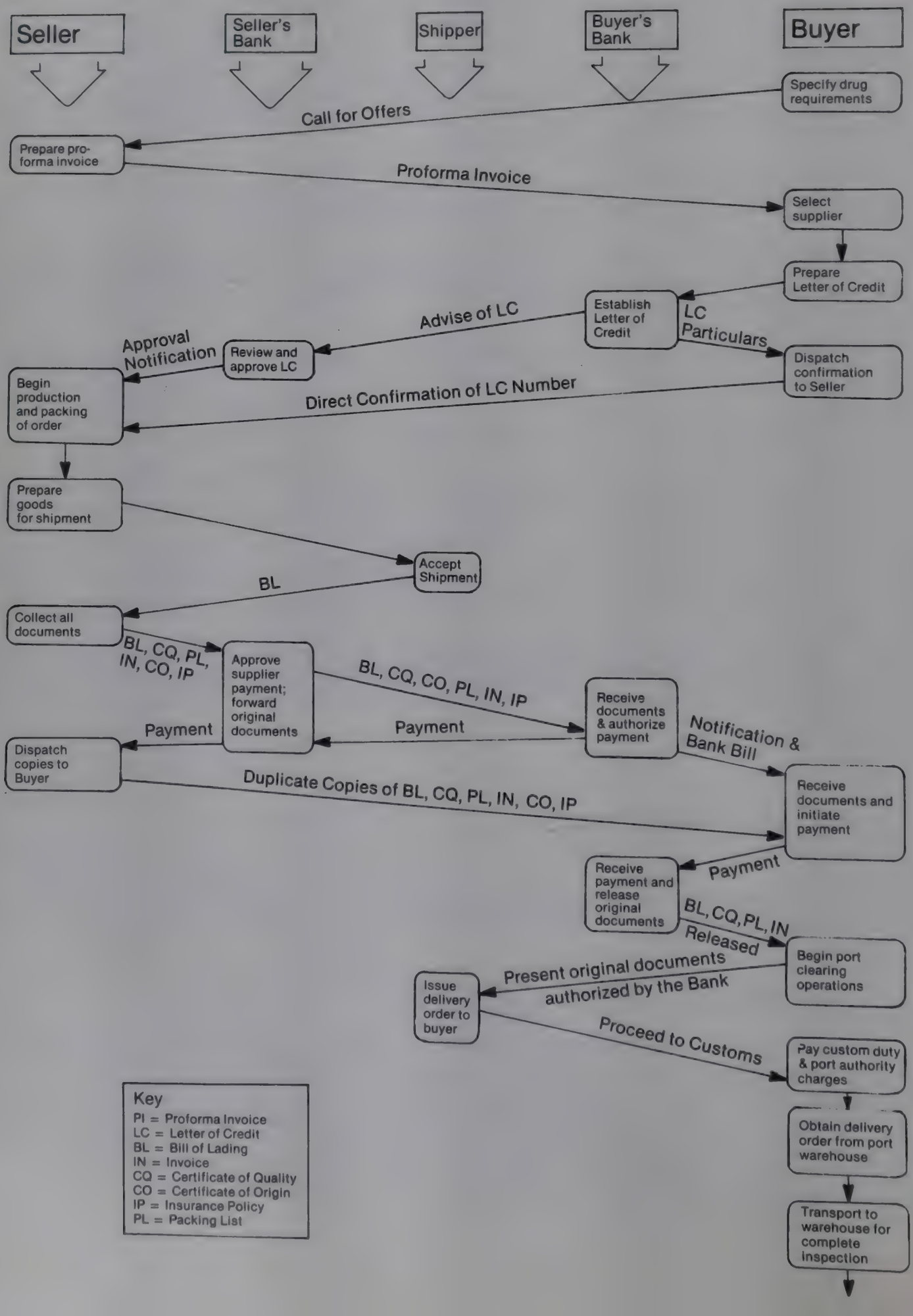


Figure IV.C.2.

Documents Used in Pharmaceutical Trade

Proforma Invoice (PI) -- Provided to the buyer by the supplier and including information such as the price of the product in the form of a C & F or CIF value, a detailed description of the product offered, and terms of payment, etc., so that the buyer can select a supplier and proceed to establish a letter of credit if necessary.

Letter of Credit (LC) -- An interbank document issued by the buyer's bank. It states that a certain sum of money is available for the seller to claim from his bank as soon as he ships a consignment and presents the required documents, as specified in the letter of credit. It becomes irrevocable when appropriated and numbered by the bank.

Bill of Lading (BL) -- A document certifying that the goods are in the charge of the carrying vessel and dated on or before the last date for shipment as given in the letter of credit. Signed by the master of the vessel; issued by the shipper.

Certificate of Quality (CQ) -- It is the usual practice for a buyer to insist on a certificate of quality to ensure that the drugs purchased conform to an acceptable standard. If the manufacturer's reliability is uncertain, it is customary for the buyer to insist on a certificate of quality issued from a well-recognized third party such as the General Superintendence.

Packing List (PL) -- Prepared by the seller, this document describes in detail the contents of each package in a consignment of drugs. The details normally include a description of the drug including its strength, pack size, the number of packs per carton, and the number of cartons per package. This helps the buyer to check whether drugs actually shipped are in accord with the packing list and the purchase contract.

Certificate of Origin (CO) -- Document stating that the product under consideration has been produced by the manufacturer in the country concerned. Such a certificate should be obtained from a national chamber of commerce or similar institute of the exporter's country.

Insurance Policy (IP) -- Drug consignments are generally insured against damage, pilferage, and complete loss. The insurance policy indicates that a certain sum of money has been paid as a premium to cover the consignment of drugs. This document would normally provide information with regard to the nature and extent of coverage provided, and terms and conditions under which it is valid.

Invoice (IN) -- Document provided by the supplier indicating costs, freight, insurance, and any other payment that is due on the order.

Bank Guarantee (BG) -- In certain circumstances, the lack of necessary documents may make it impossible for the buyer to clear the consignment of drugs which has arrived at the port. In such instances it is sometimes necessary to obtain a bank guarantee from the buyer's bank in order to complete port-clearing.

Bank Bill (BB) -- A bill presented by the buyer's bank to the buyer which covers total cost of goods received and any bank charges for processing the order (cable charges, interest on LC, fees).

b. Locating the Shipments

Information can also be obtained from the local agents as to where, specifically, the shipment will arrive (i.e., what quay or airport), and subsequently the specific port or customs warehouse to which the consignment is cleared.

c. Obtaining Documents Needed for Clearing

The port authorities require the original copies of the documents detailed in Figure IV.C.2. to permit clearance by the buyer. Along with these documents the buyer prepares Customs and Port Authority Entries. Once this is completed, customs duties (if applicable) as well as Port Authority and other charges

must be paid before removal of the consignment of drugs from the custody of the customs and port authorities.

Further details regarding the processing of documents are illustrated graphically in Figure IV.C.1.

ASSESSMENT GUIDE IV.C.
Importation and Port-Clearing Activities

- What air, sea, and land ports do public drug supplies come through? What proportion of the total supplies come through each of the ports?
- What is the average length of time between the arrival of a drug in the port and its release for transport from the port to the central medical stores?
- What are the storage conditions at the port(s)? Are there cold rooms? Freezers? Locked warehouses? Chained fences? What is the environment of the port like? Is there always a wet sea mist, for example?
- What losses occur in the port due to damage? Theft? Poor storage conditions? Inability to locate shipments because of crowding or disorganized port management?
- Who is responsible for port-clearing? Private import agents? Central medical stores clerks? An import unit within the Ministry of Health pharmaceuticals program? A separate government office?
- Are drugs given any special priority with regard to storage conditions and the expediency of port-clearing? What is the effect of government customs and import control regulations on the efficiency of port-clearing? Do other ministries and government agencies facilitate or impede port-clearing?
- Do the individuals responsible for port-clearing know in advance when and where a shipment is due? Is this information used to expedite port-clearance? How do the responsible individuals coordinate the activities of those engaged in port-clearing?
- Do the individuals engaged in port-clearing receive formal training in import documentation and port-clearing procedures?
- Does the number of drug consignments vary significantly throughout the year? If so, does this variation in workload create any difficulty with the port-clearing staff?

d. Delivery to Warehouse

Except for drugs requiring special storage conditions, such as a cool room or a dark location, the consignment is kept in a general-purpose port or customs warehouse until delivery. The loading of the consignment onto trucks must be supervised by wharf officers and drivers instructed to proceed to the exact stores to which the consignment should be delivered.

2. EXPEDITING PORT-CLEARING

Even though port facilities in many developing countries do not favor efficient clearing of drugs, the port-clearing department can improve the situation by utilizing better systems and procedures. Typical problems experienced by an Import Unit with some methods for expediting work are discussed below.

a. Use of an Activity Monitoring System

One of the biggest problems experienced by a manager in charge of an import unit or port-clearing department is the supervision of staff engaged in clearing of drugs at the port. Unlike other functional departments such as procurement and inventory control, many of the persons involved in clearing drugs have to work long hours outside the office. Hence, supervision, assignment of duties, and progress control become rather difficult.

Under such conditions it is helpful if the import manager maintains an information system at his office which is capable of monitoring current port-clearing activities, causes of delays, and assignments of personnel. Such a system should expedite the clearing of urgently needed consignments.

One such system, using a manually operated control box, has been successfully introduced into the State Pharmaceuticals Corporation of Sri Lanka (Country Study IV.C.1.).

b. Acquiring Information Regarding Expected Consignments

Another major problem is the lack of sufficient information on expected shipments so that work can be scheduled well in advance. In many instances the Import Unit learns of the arrival of consignments only after the goods have actually landed and in some cases after having incurred high demurrage charges. It is also common for the Import Unit to spend a great deal of time checking with shipping agents to ascertain whether the goods have arrived.

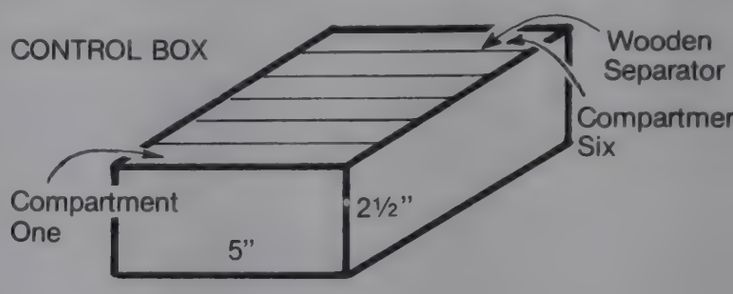
Unnecessary demurrage charges and expenditure of staff time are usually caused by a breakdown of communication between the supplier and the purchasing department. If the standard form letters described in Appendix III.B.2. are used, it should help the Import Unit to obtain timely information on expected shipments.

Country Study IV.C.1.

A Manually Operated Control Box to Expedite Port Clearance

The State Pharmaceutical Corporation of Sri Lanka, during its first few years of operation, experienced frequent stockouts of drugs. In many instances the drugs which were out of stock were awaiting clearance at the port, but could not be made available for distribution due to delays in the clearing process. To improve the operations of the Wharf Department many new systems and procedures were introduced, including a manually operated control box.

The Control Box -- The system consists of a six-compartment Control Box and a set of Control Cards and is linked to the order status monitoring system described in Country Study III.B.2. As soon as a reply to Standard Letter No.3 regarding shipping information is received by the Supply Department (Appendix III.B.2.), the information is passed to the Wharf Department and a Control Card (see below) is prepared and introduced into the first compartment.



The next step is to obtain the original and copy documents in required number from the Supply Department and to prepare the other documents necessary for port-clearing.

As each step in the process is completed, the Control Card is moved to the next compartment in the Control Box. The activities associated with each compartment are listed below.

Compartment Number	Significance of Card Stationed in the Compartment
1	An expected shipment. For each expected shipment a card is prepared, indicating the Due Date, Indent Number, Vessel, etc. (see below).
2	Documents not in order. Information regarding the shipment has not been provided by the Supply Department.
3	Documents necessary for clearing are being processed at the Wharf Department.
4	Awaiting arrival of vessel.
5	All documents in order, awaiting clearance.
6	Consignment cleared and a wharf note issued.

Setting Priorities for Clearing -- When many consignments are awaiting clearance at the port, a system of assigning priorities for clearance is needed. Color-coding of control cards serves this purpose. White cards in the control box represent all normal deliveries; red cards represent any air freight consignments or emergency shipments; green cards are for drugs which require refrigeration and, therefore, must be given top priority in the clearing schedule.

Conclusion -- Maintaining the control box serves as a powerful tool to control the activities of the Wharf Department. Further, this method of control gives the Manager of this Department ample opportunity to schedule his work well in advance and to reallocate facilities and manpower to jobs with high priority.

Cards Used in Control Boxes at the Wharf Department

SIDE 1

PORT-CLEARANCE CONTROL CARD

Indent Supplier

Vessel Due Date

Expected Contents:

Remarks:

Underwriters: Premium:

Value of Claim:

	CLAIM	RECEIPTS	VARIANCE
(A) Steamer Agents:			
(B) Suppliers:			
(C) Underwriters:			
TOTAL			

REMARKS:

SIDE 2

c. Obtaining Necessary Documents

Another problem which causes many delays is the lack of proper documents necessary for clearing consignments. Often, documents needed for clearing are not received from suppliers or are not available in correct numbers. This results in additional delay and expense. There is very little that can be done to overcome this problem, except to incorporate reports of such supplier inefficiency in the general merit rating system of suppliers (Chapter III.C.).

3. PRESSING INSURANCE CLAIMS

An important part of the procurement and importation process is the initiation and completion of insurance claims for damaged, short-shipped, or otherwise substandard shipments. The following 1976 listing of insurance claims for one large national drug importation program illustrates the magnitude of recoverable damages:

Category	Value of Claims
Damaged, Broken	U.S.$ 27,480.
Short-Shipped	$ 3,065.
Packing Error	$ 435.
Short-Landed	$ 2,800.
TOTAL	$ 33,780.

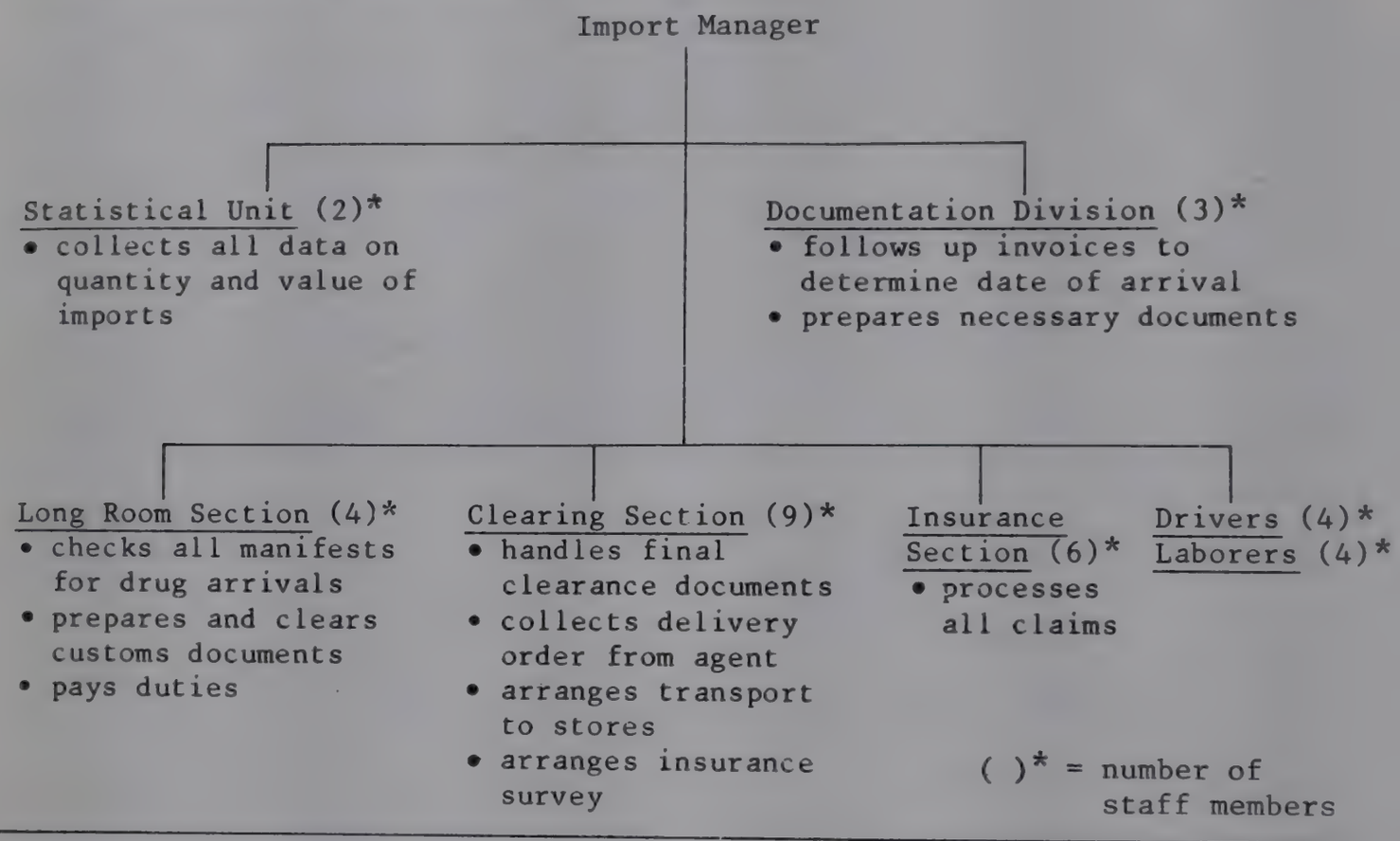
Although this total represents only 2% of the U.S.$1,788,380. landed value of 1976 imports, the absolute value of the losses which would have occurred unless the claims had been pressed is substantial.

Recovery of insured losses depends upon the existence of a conscientious, systematic routine for inspecting all shipments when they are accepted at the port or at the central warehouse. Procedures similar to those described in the following chapter should be used, and inspectors should be closely supervised.

Consistent recovery of insured losses also depends upon the assignment of qualified staff to claims processing. Their work can be facilitated by the institution of a hand-operated monitoring system similar to the one used for port-clearing. This would reduce the chance that claims would be forgotten or unduly delayed.

Figure IV.C.3.

Organization of an Import Unit


Import Manager
Statistical Unit (2)*
• collects all data on quantity and value of imports
Documentation Division (3)*
• follows up invoices to determine date of arrival
• prepares necessary documents
Long Room Section (4)*
• checks all manifests for drug arrivals
• prepares and clears customs documents
• pays duties
Clearing Section (9)*
• handles final clearance documents
• collects delivery order from agent
• arranges transport to stores
• arranges insurance survey
Insurance Section (6)*
• processes all claims
Drivers (4)*
Laborers (4)*
( )* = number of staff members

4. IMPACT OF GOVERNMENT CUSTOMS AND IMPORTATION REGULATIONS ON THE EFFICIENCY AND ECONOMY OF PORT-CLEARING

While government customs and import regulations vary from one country to another, the efficiency and economy of port-clearing is greatly hindered by poor systems and procedures used by customs and port authorities in many countries. Resulting delays for importers are substantial, yet there is little that can be done to overcome this situation. The common practice adopted by private companies and individual importers is to obtain the services of a clearing agent, who usually has some arrangement with port officers to expedite the clearing of goods. In the case of public institutions, administrative and financial regulations often make it impossible to adopt such a practice. Therefore, consignments belonging to these organizations frequently get a very low priority for clearing.

In order to overcome this problem some public sector institutions are handing over the task of port-clearing to private companies on a contract basis. If such a procedure is adopted, it is also important to strengthen the security system, as experience indicates that the probability of pilferage increases when the task of clearing and delivery from the port to the warehouse is handled by private companies.

5. ORGANIZING AN IMPORT UNIT

Responsibility for the clearing of drug shipments from land, sea, and air ports may rest with a separate unit of a national drug supply program, with a separate division within the Ministry of Health, with a different ministry, or with a private firm entirely outside the government. This responsibility should be specifically defined and the responsible officials should be accountable to the drug supply program for prompt, reliable port-clearance. Figure IV.C.3. shows the organization of the import unit for one large national drug supply program.

Although most port-clearing functions can be performed by trained clerical staff, the specific procedures should be established by an individual experienced in import management. To achieve efficient port-clearing, these procedures must take into consideration the idiosyncracies of local port conditions and of the individual drug supply program.

SUMMARY

Port delays can be costly. Types of loses include:

- reduced shelf-life or, with vaccines, complete loss of potency;
- increased pilferage;
- demurrage fees;
- stockouts unless safety stock levels are increased;
- cash flow problems because drugs are tied up in port.

The port-clearing process consists of:

(1) Identifying the arrival of shipments;
(2) Locating the shipments;
(3) Obtaining documents needed for clearing;
(4) Delivery of goods to the warehouse.

Expediting port-clearing is an important function of the Import Unit. Use of a simple, hand-operated activity monitoring system can facilitate this function.

Losses and damages in transit can be substantial. To recover insured losses, the Import Unit must systematically and expeditiously press insurance claims.

The impact of government customs and import regulations on port-clearing can be significant; private companies are sometimes able to achieve more rapid port-clearance.

As in other aspects of drug supply management, sufficient numbers of experienced and well-trained staff can significantly improve the port-clearing process.

CHAPTER IV.C. REFERENCES

Dias, V.: Re-Organization of Import and Wharf Departments, State Pharmaceuticals Corporation Report No. 2. Colombo, Sri Lanka: National Institute of Management, 1975.

International Chamber of Commerce: International Rules for the Interpretation of Trade Terms. Paris: International Chamber of Commerce, 1977. (English-French).

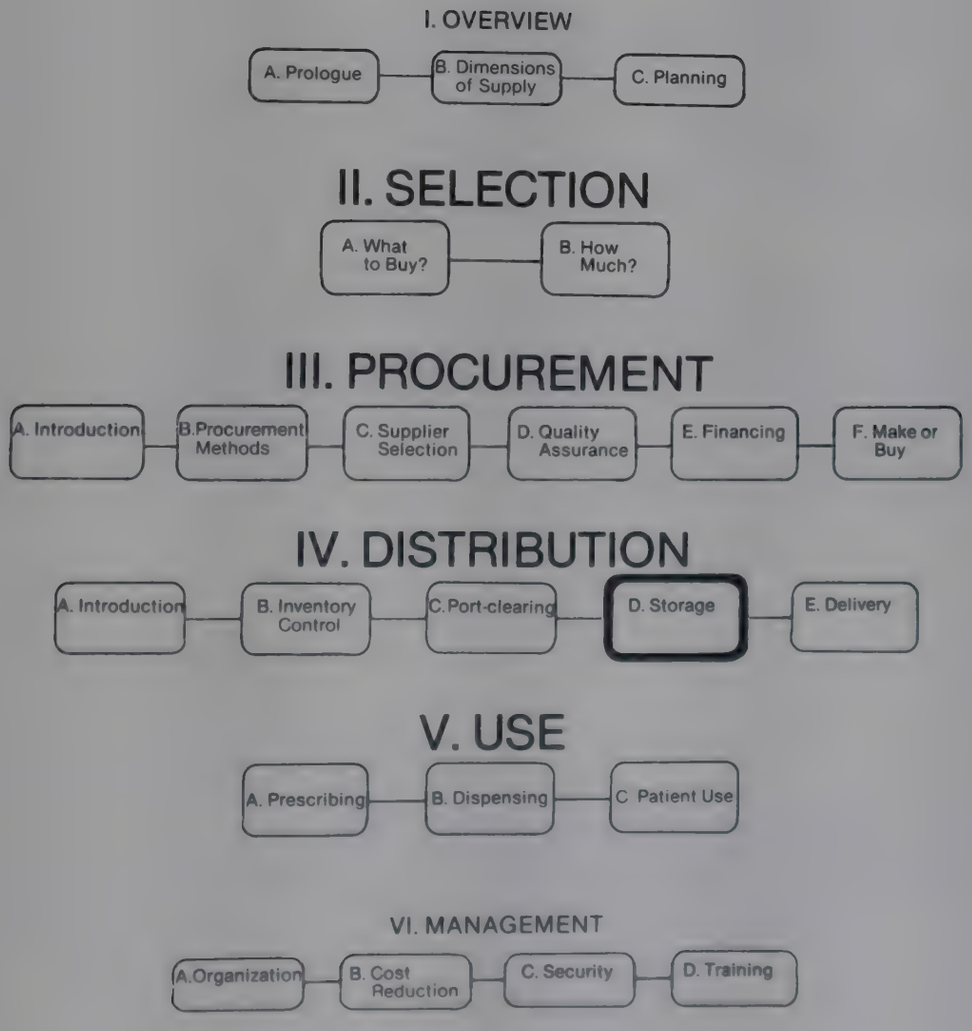
Taff, C.A.: Management of Physical Distribution and Transportation. Chapter 13, International Distribution. Homewood, IL.: Richard D. Irwin, Inc., 1972.

United Nations: Shipping in the Seventies. New York: United Nations Conference on Trade and Development, 1972.

United Nations: Customs Organization and Administration in Developing Countries: Major Considerations. New York: United Nations Department of Economic and Social Affairs, 1977.

Chapter IV.D.

Design and Operation of Storage Facilities



	Page
1. THE PHYSICAL STRUCTURE	337
a. Establishing the Distribution Hierarchy	337
b. Location of Medical Stores	344
c. Site Selection	346
2. WAREHOUSE DESIGN PRINCIPLES	346
3. WAREHOUSE STAFFING AND PROCEDURES	352
a. Receiving and Storage	353
b. Issuing	355
c. Shipping	357
d. Inventory Taking	359
4. PROMOTING EFFICIENCY WITHIN WAREHOUSES	359
a. Working Conditions	360
b. Written Materials	360
c. Supervision	360
d. Training	361
5. STORAGE AND STOCK CONTROL AT CLINICAL FACILITIES	362
6. ESTABLISHING TYPES AND AMOUNTS OF DRUGS TO STOCK AT EACH LEVEL	363
7. MAINTAINING THE COLD CHAIN	364
SUMMARY	366
REFERENCES	367
APPENDICES	
IV.D.1. Sample Stock Replenishment Request	369
IV.D.2. Sample Receiving Report	370
IV.D.3. Sample Requisition/Issue Ticket	371
IV.D.4. Sample Bin Card	372
IV.D.5. Sample Delivery Voucher	373
IV.D.6. Sample Refrigerator Control Card	374
IV.D.7. Sample Internal Requisition	375

Design and Operation of Storage Facilities

Optimal use of storage and delivery resources depends on sound decision-making and timely performance in other areas of the supply system, including product selection, budgetary planning, and procurement. But careful drug selection and wise procurement practices are of no consequence for public health unless the distribution network can properly store and regularly deliver drugs to all health facilities. Few physicians and pharmacists and even fewer auxiliary nurses and village health workers participate in the development of drug formularies or other planning activities, but empty storerooms and erratic delivery of drugs frequently confront all of these workers.

In many public health systems, storage and transport of supplies rank low as budgetary and planning priorities. Reasons for this are best sought in the predominance of clinically oriented physicians in key management positions, in chronic financial constraints, and in the low professional status accorded to stock clerks, porters, and truck drivers. The tendency to neglect distribution activities is unfortunate because storage and delivery are two areas in which low-cost tangible improvements can be made -- and often very quickly. Warehouses (medical stores) are relatively inexpensive to construct or renovate; more rational management of existing transport resources can markedly improve delivery; and more careful supervision of distribution staff can significantly reduce drug wastage.

Assessment Guide IV.D. introduces many of the issues to be considered in the evaluation of a country's distribution network and the operation of storage facilities. The main objectives of an effective system for storage and delivery are summarized in Figure IV.D.1. This figure might serve as the starting point for planning a new system or designing improvements in an existing sytem.

1. THE PHYSICAL STRUCTURE

a. Establishing the Distribution Hierarchy

A basic requirement of system design is determining the number of levels in the distribution hierarchy and the delivery paths among these facilities. Factors that influence this decision include:

- Number and geographical distribution of clinical facilities
- Effect of route and distance on the time it takes to reach these facilities
- Number, types, and capacities of existing storage facilities
- Management capabilities at various levels
- Transport alternatives, their relative costs, and their dependability.

ASSESSMENT GUIDE IV.D.
The Distribution Network and Storage Facilities

Distribution Network

- How many clinical facilities are presently served by the system? How is the distribution network arranged? How many levels are there in the distribution hierarchy? How are the storage points linked? How is each clinical and storage facility supplied?

- How extensive is the geographic dispersion of the clinical facilities? What are the distinctive features of the pattern of distribution?

- What are the average times and mileage between warehouses and clinical facilities? Are travel times affected more by distance or route conditions? Are there significant regional variations in travel times?

- Where are the principal sources of pharmaceuticals located? Are they concentrated in one place? Dispersed? What are the potential contributions of individual suppliers to the system in terms of products? Storage capacity? Transport?

Storage

- How well does the warehouse move and store supplies? Are there particular problems associated with building design? Equipment? Personnel?

- How is the warehouse organized? What are the different offices and sections? What does each do? What would an organogram of the present staffing pattern look like?

- How would you rate the performance of basic routines for receiving, storage, and shipping? What are the principal problems associated with each? Weak staff? Procedures?

- What forms are currently used in the warehouse? What is your assessment of present documentation procedures? How long does it take to process a requisition and prepare a shipment? How long would it take to determine the quantities of each supply item now in stock?

- Does the central Ministry have any responsibility for enforcing storage and control procedures at regional and district warehouses and clinical facilities? Who is responsible for this activity?

Figure IV.D.1.

Elements of System Design

Objectives:	Factors to consider
ESTABLISH THE HIERARCHY Work toward a system that is simple to manage and minimizes costs, while providing good service.	• Number and geographical distribution of clinical facilities • The time it takes to reach facilities • Number, types, and capacities of existing storage points • Managerial capacities at various levels • Transport alternatives and their relative costs
LOCATE STORAGE FACILITIES Locate warehouses to facilitate movement of drugs from sources to patients	• Location of sources • Number and location of clinical facilities • Transport links between sources and clinical facilities • Transshipment requirements • Seasonal closing of routes • Careful selection of the building site
DEVELOP SUPPLY MANAGEMENT CAPABILITY Work toward an uncomplicated approach that moves supplies efficiently and provides reliable information for control and management decision-making.	• Principles of warehouse design and internal organization • Staffing and procedures • Effective personnel management • Supply management at clinical facilities
DEVELOP DELIVERY CAPACITY Develop a flexible system that uses available resources to provide reliable service at low cost.	• Existing transport resources and their costs • Vehicle maintenance procedures • Coordination of delivery intervals, stock levels, schedules, and routes

There is no universal optimal design. The role of the distribution system is to provide good service to patients by minimizing stockouts of drugs through regular, scheduled deliveries. Since budgetary constraints and scarcity of managerial talent are almost universal, perhaps the only safe generalization is to "work towards a system that is simple to manage, and minimizes costs, while providing an acceptable level of service". Since needs, resources, and constraints vary considerably from country to country, the number of levels and storage facilities in the hierarchy must be determined on an individual basis.

Country Study IV.D.1. illustrates some of the variability which is possible in system design. In each country, the structure of the distribution network evolved to meet certain local needs or constraints. And in each case the distribution network was in a state of continuing evolution as existing constraints were recognized and attempts were made to meet new needs.

Comparison of Alternative Distribution Networks

Figure IV.D.2. shows four alternative distribution networks, which are prototypes based on the distribution systems described in Country Study IV.D.1. Also noted are the average inventories in the four networks; these are hypothetical estimates based on an annual consumption of U.S.$1,000,000 worth of drugs. The estimates assume that the drug list is divided by level-of-use so that only certain drugs are stocked and dispensed at the lower levels, and that adequate safety stock is maintained in order to assure no more than a 5% stockout rate with moderate variability in demand and in delivery. The estimates also assume that drugs are delivered every six months to the highest level stock points, every three months from central to regional facilities, every two months from hospitals to health centers, and monthly to aid posts.

Networks A and B are three-level networks, while networks C and D are four-level networks. It is apparent that the addition of another level to the distribution network carries significant implications in terms of the amount of inventory required to maintain necessary working stock and safety stock. Comparison of network A with network B and network C with network D demonstrates that additional safety stock may be required when regional storage points (regional medical stores) are entirely separate from clinical facilities (regional and district hospitals).

Choosing the Best Distribution Hierarchy

Choosing the number of levels for a distribution system and determining the types of storage facilities at each level is a complex process. Figure IV.D.3. compares the most common patterns, three-level and four-level systems, in terms of several factors that are important to consider. Three-level systems are usually less expensive to set up and to operate, and they are generally easier to manage. However, where travel time and geographic separation are great, four-level systems will often provide better service. In such circumstances four-level systems may even be less expensive to operate, since they may reduce the need to airlift supplies during rainy seasons or epidemics in individual districts.

Country Study IV.D.1.

Distribution Networks in Selected Countries

Peru -- The Basic Medicines Program maintains no central warehouse and there is no government transportation network for delivering drugs to the 57 Area Hospitals. Instead, distribution occurs through the commercial sector. This is made possible by the existence of 36 Peruvian drug firms, 19 subsidiaries of multinational firms, and a reasonably well-developed private distribution network which reaches a large proportion of the country.

Every two years the Basic Medicines Program collects estimates of drug requirements from the Area Hospitals, conducts a public tender, and awards two-year supply contracts. Each supplier then receives a quarterly listing which indicates the quantity of each drug to be delivered to each of the 57 Area Hospitals. Monthly supplementary deliveries are sometimes needed, and Area Hospitals can arrange transfers of drugs among one another. From the Area Hospitals drugs are issued to 100 local hospitals and over 300 health centers. These facilities then supply about 1000 health posts. Some Area Hospitals have special transportation resources, but often drugs are carried by the doctor or health worker from the hospitals to the health centers and health posts. (1977)

Papua New Guinea -- Consisting of one large but topographically divided land mass and many smaller islands, Papua New Guinea (PNG) is highly dependent upon air and sea transportation. In response to this geographic diversity and disjointed transportation network, the Ministry of Health established regional stores at five seaport locations and one inland location.

PNG is almost completely reliant upon foreign sources for finished dose products and pharmacy raw materials. When contracts are negotiated, divided shipments to each of the regional stores are specified. About 80% of all supplies are shipped directly from the supplier to the regional medical stores. The remainder of the shipments are generally low-volume, low-value items which are delivered to the medical store in the capital city for subsequent redistribution. Suppliers who find that distribution to multiple ports adds significantly to their expenses will sometimes make an offer which specifies a single delivery port only. The tender board then has the option of selecting a more costly offer with divided delivery. Following a system of regulated indenting (Country Study IV.B.1.), orders from the regional stores are collated by the central office and placed three times per year.

From the regional stores drugs are delivered by land, sea, or air to the 20 hospitals monthly and to the nearly 200 health centers every two months. Supplies for the 1700 aid posts are generally collected every two weeks by the aid post orderlies when they come to the health center or hospitals for their paychecks. Delivery may take up to eight weeks to the most peripheral locations, but one to three week delivery times are more common. (1978)

Tanzania -- Over 90% of the drugs used in Tanzania are imported in finished dose form. They are received at the capital seaport or airport and are brought to the government Central Medical Stores (CMS) for distribution. From the CMS drugs are dispatched by railway, by truck, and, occasionally, by air to the 25 regional hospitals. Regional hospitals are expected to requisition drugs on a quarterly basis, but some order bi-annually. Distribution from the regional hospitals to the nearly 200 district hospitals and health centers is the responsibility of the individual regions and follows varied patterns throughout the country.

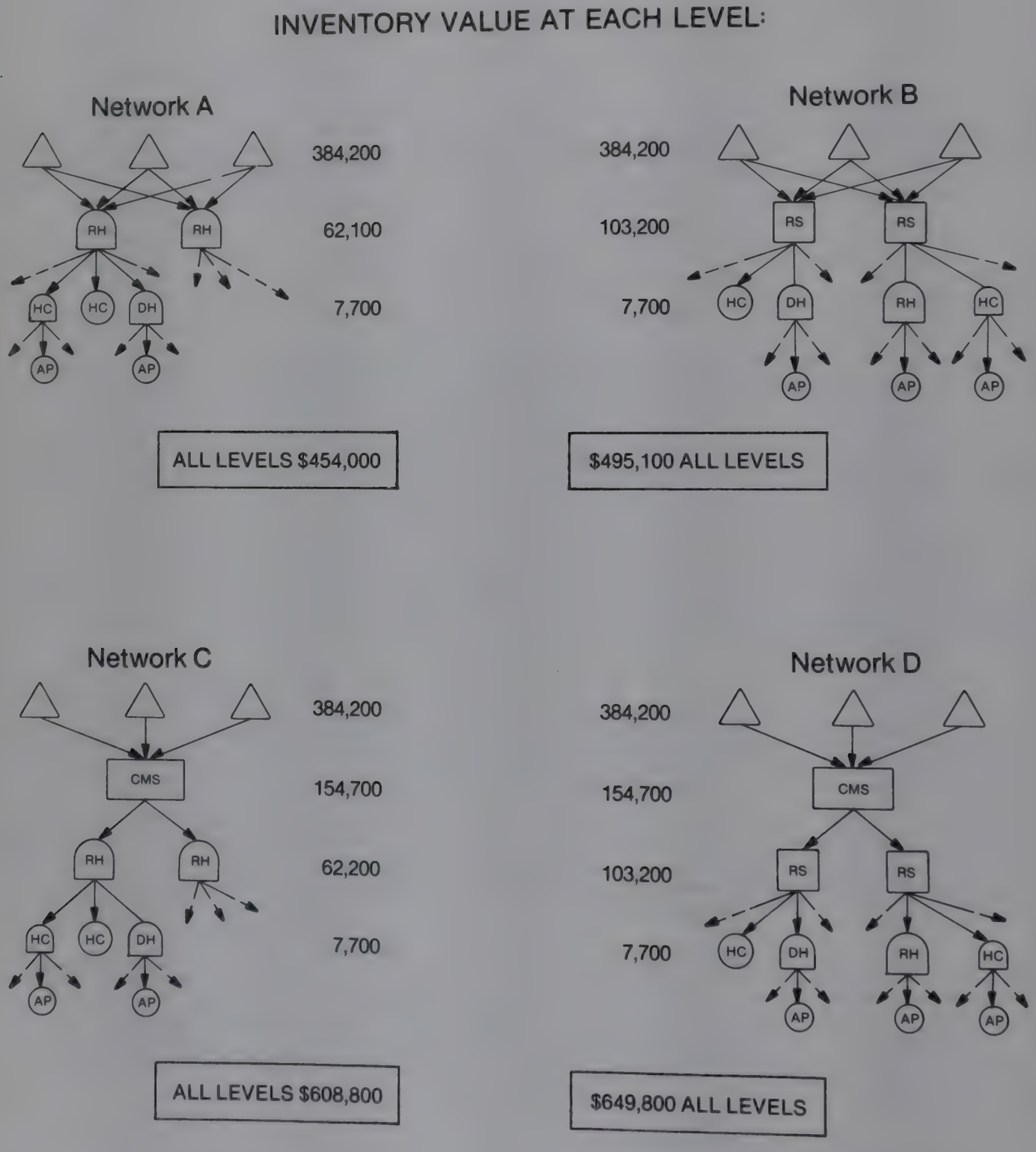
Transportation remains a major distribution problem. Railways are not fully utilized, and highway transportation is unreliable because large portions of the country are cut off from the coast during the rainy season, when roads are impassable. To provide more dependable supplies of drugs and to decrease congestion at the CMS, a plan has been developed for the creation of four regional stores. (1978)

Malaysia -- Drugs for public health care services are provided through the national Government Medical Stores (GMS) and a system of State Medical Stores (SMS). Supply contracts are negotiated by the GMS with local manufacturers and representatives of foreign suppliers. All goods are delivered to one of the main ports and transported to the GMS warehouse. Quarterly requisitions are received from the 13 SMS. Because of the large volume of drugs supplied to each SMS, the states make weekly pick-ups. The availability of vehicles and good highways makes it possible for most SMS to send their own transport to collect the supplies from the GMS. A systematic pick-up schedule facilitates this process. Bulk items are sent by railroad, and shipments to East Malaysia go by sea.

Using their own transport, the SMS make weekly, monthly, or quarterly deliveries to the 12 general hospitals and over 400 district hospitals and health centers. From these facilities, drugs are forwarded in available hospital and health center transportation to nearly 1500 health subcenters, clinics, and rural community centers. A typical SMS has two to four trucks of its own to handle the collection and distribution of medical supplies. A good cold chain is maintained from the GMS to the health centers. Operating refrigerators exist at most facilities and the GMS provides insulated dry-ice-cooled boxes which are used to transport vaccines to the state stores and from there to the districts. (1978)

Figure IV. D. 2.

Average Inventory Values for Four Distribution Networks



Key: △ = Supply Source; □ = Storage Facility; ⌓ = Storage & Clinical Facility; ○ = Clinical Facility

CMS = Central Medical Store
RS = Regional Store
RH = Regional Hospital
DH = District Hospital
HC = Health Center
AP = Aid Post

Adapted from Quick, 1978.

Figure IV.D.3.

Comparison of Three-Level and Four-Level Distribution Hierarchies

FACTORS	THREE-LEVEL	FOUR-LEVEL	COMMENTS
Management Complexity	Less complex	More complex	Four-level systems are more likely to have processing, delivery, and inventory control problems at the periphery.
Set-up Costs • Buildings • Equipment • Vehicles	Lower	Higher	In regions where clinical facilities are relatively numerous and/or widely dispersed, the costs of a four-level system may well be justified.
Operating Costs • Personnel • Utilities • Fuel • Expendable supplies	Lower	Higher	The same observation as above.
Inventory Holding Costs	Lower	Higher	If a four-level system results in more dependable delivery, then lower safety stock is needed and inventory holding costs are not as high as expected.
Distribution of Clinical Facilities	Three-level preferable with denser distribution	Four-level often useful with sparser distribution	Distance can be measured in kilometers (miles), time, or transportation cost. Thus, an area that is small in square kilometers but is burdened with long travel times may benefit from a four-level system.
Quality of Service • Number of stockouts • Ratio of interim and emergency to regular deliveries	Variable, depending on the location of storage and clinical facilities and the reliability of transportation between facilities		Inventory control and delivery are harder to manage in extended systems, but with good management such systems are more responsive to the needs of remote facilities.

Since there is no foolproof method for establishing the optimal number of levels and facilities in the distribution system, the following steps may provide a useful way of arriving at the "best" hierarchy for an individual country or program:

(1) Diagram the existing distribution hierarchy (include all clinical and storage facilities and the supply lines connecting them).

(2) Diagram three to six feasible alternative hierarchies (include patterns based on different linkages between existing facilities as well as patterns which require additional facilities).

(3) For each of these alternatives, estimate as accurately as possible the values for the factors listed in Figure IV.D.3. (management complexity, set-up costs, operating costs, inventory holding costs, delivery times, etc.).

(4) Select and implement the system which provides the best quality of service with available funds.

This systematic approach may identify previously unrecognized possibilities for improving distribution. Furthermore, steps 1-3 may provide information which can be used to substantiate requests to senior officials or external aid sources for additional funds. Such funds may make it possible to implement one of the more costly, but more effective, plans.

b. Location of Medical Stores

The placement of medical stores or warehouses can be described in terms of location and site. Location refers to the city, town, or other geographic division in which the warehouse is placed. Warehouse locations are determined in light of the locations of all other warehouses and supply points throughout the country. Site selection means choosing the specific piece of land on which the storage facility will be built, or the building to be used for storage.

Because the distribution system is, in effect, the link between sources of pharmaceuticals (manufacturers, distributors, donors), and the users of these products (patients at clinical facilities), the principal objective in positioning warehouses is to promote the fastest and least expensive transport of supplies from source to user. The factors to consider are familiar:

- Location of supply sources
- Number and location of clinical facilities
- Transport links (road, rail, air, sea) between sources and clinical facilities
- Transshipment requirements for land, water, air, or air mail transport
- Seasonal factors that cut routes
- Number, type, and capacity of existing storage facilities.

To determine warehouse locations planners need to study existing maps, identify supply sources, investigate transport options and, finally, select the places that will efficiently serve as many clinical facilities as possible.

The discussion thus far has assumed storage and delivery radiating out from one central warehouse that serves as the inlet for all supplies flowing through the system. This centralized approach makes sense in countries where sources are heavily concentrated in one city. Haiti is a good example of this case. Virtually all sources are located in the capital city of Port-au-Prince. The central warehouse directly supplies regional warehouses located at strategic points on main highways that give them access to interior road networks. Tanzania and Malaysia are other countries in which a single central warehouse is most reasonable (Country Study IV.D.1.).

Papua New Guinea presents a contrasting case (Country Study IV.D.1.). Like Haiti, it imports nearly all of its pharmaceutical supplies. It is a geographically divided country and its ragged coastline provides five ports at which ships can deliver supplies for redistribution. Papua New Guinea's case argues for a decentralized approach to warehouse positioning and system design. Several top level warehouses could be set up near sources (ports or commercial outlets) for distribution to lower levels of the hierarchy. Each of these subsystems might have different numbers of levels, as each serves a different region with different local conditions. All of the factors discussed in the preceding section still apply. With a coordinated information system, the central ministry can monitor the flow of supplies into any point of the system by requiring duplicate invoices from sources. In Papua New Guinea it is neither necessary nor desirable to channel all incoming supplies through one central warehouse located in the capital city of Port Moresby.

A point of special consideration is the storage requirements for transshipment (shipment of supplies to an intermediate location, from which they are forwarded by another means of transport to another major storage facility). Warehouses are usually thought of as points of redistribution to multiple lower level facilities. And, in fact, warehouses that transship from one form of transport to another frequently perform this function. This occurs, for example, at a sea port where supplies are taken off ships, stored, and redistributed by motor or rail transport. In other cases, warehouses for transshipping perform a "pass through" function. A river port, not well located for redistribution, may require a warehouse to temporarily store supplies until vehicles can pick them up and transfer them on to a well-located redistribution point.

To avoid delays or congestion at unexpected points in the distribution network, transshipment points should be identified in advance and adequacy of storage facilities should be assured.

A final factor to consider is the effect of seasonal cuts on routes. Where mountain passes fill with snow, or rivers become too dangerous to cross, warehouses may be required on either side of these barriers. This is another decision that must be made on an individual basis in the context of the whole system design.

c. Site Selection

After determining the geographic locations of warehouses, the next problem to be solved is site selection. At each location, warehouses should be built on sites that enhance their ability to receive, safeguard, and redistribute supplies. Careful consideration should be given to such factors as access, drainage, security, water, and electrical and telephone service (Figure IV.D.4.). Deficiencies in any of these factors may limit the utility of the warehouse, cause stock damage, or both. Warehouses that are geographically positioned to take advantage of seaports, airports, railways, or highways should be built on land that gives them ready access to these links.

Entry and exit should be unrestricted, and the site must be large enough for parking vehicles while allowing free movement to and from the main entrance Enclosed yards promote security of vehicles and stock. Good drainage has been mentioned and it applies to access routes as well as the site itself. The road in and out must be open the year round. (In one South American country, a warehouse that is sensibly positioned geographically becomes an island in a lake each rainy season. Recently, when workers finally gained access after a long rainy season, they discovered that thieves had taken most of the stock.)

Land that meets all needs may be expensive, especially in commercial centers, but warehouses must not be built on unsuitable sites; the long-term savings from wise site selection can be considerable.

2. WAREHOUSE DESIGN PRINCIPLES

As with warehouse location and siting, warehouse design should be undertaken thoughtfully and with certain specific design characteristics in mind (Figure IV.D.5.). The previous section discussed the importance of ease of entry and exit for warehouses. The same principle holds within the buildings themselves. Interior storage space should facilitate movement of supplies. Unless adequate stock elevators are available, one-floor layouts are recommended. A large control storage area offers the most flexibility for stock arrangement. If, however, the warehouse is divided into a number of storerooms by interior walls, doorways shoud be wide and well positioned to allow free movement of supplies throughout the building. Figure IV.D.6. is a sample warehouse layout.

Basic Design

One important principle is to allow for sufficient internal air circulatio Good circulation maximizes shelf-life of expendable supplies, particularly pharmaceuticals. Although air conditioning is ideal, it is expensive to operate for large storage areas. Ceiling fans provide a practical alternative. Where they are not adequate, forced ventilation through the roof is recommended

Good circulation has other positive effects. In one Caribbean country, the central warehouse is located in a dusty zone near the waterfront. To keep out dust the windows are kept closed at all times. But the building has no fans, and because of the sheet metal roof, the central storage area becomes

Figure IV.D.4.

Checklist for Warehouse Site Selection

- ☑ ACCESSIBILITY -- road is open the year round.
- ☑ UTILITIES -- site served by water and electricity.
- ☑ COMMUNICATIONS -- reliable telephone service.
- ☑ DRAINAGE -- neither site nor surrounding area subject to flooding due to direct runoff or high water table.
- ☑ SIZE -- unimpaired entry and exit for large vehicles, ample parking.
- ☑ SECURITY -- area not likely to invite intrusion or vandalism.
- ☑ PROXIMITY -- good access to transport links, seaports, airports, railways, highways.

Figure IV.D.5.

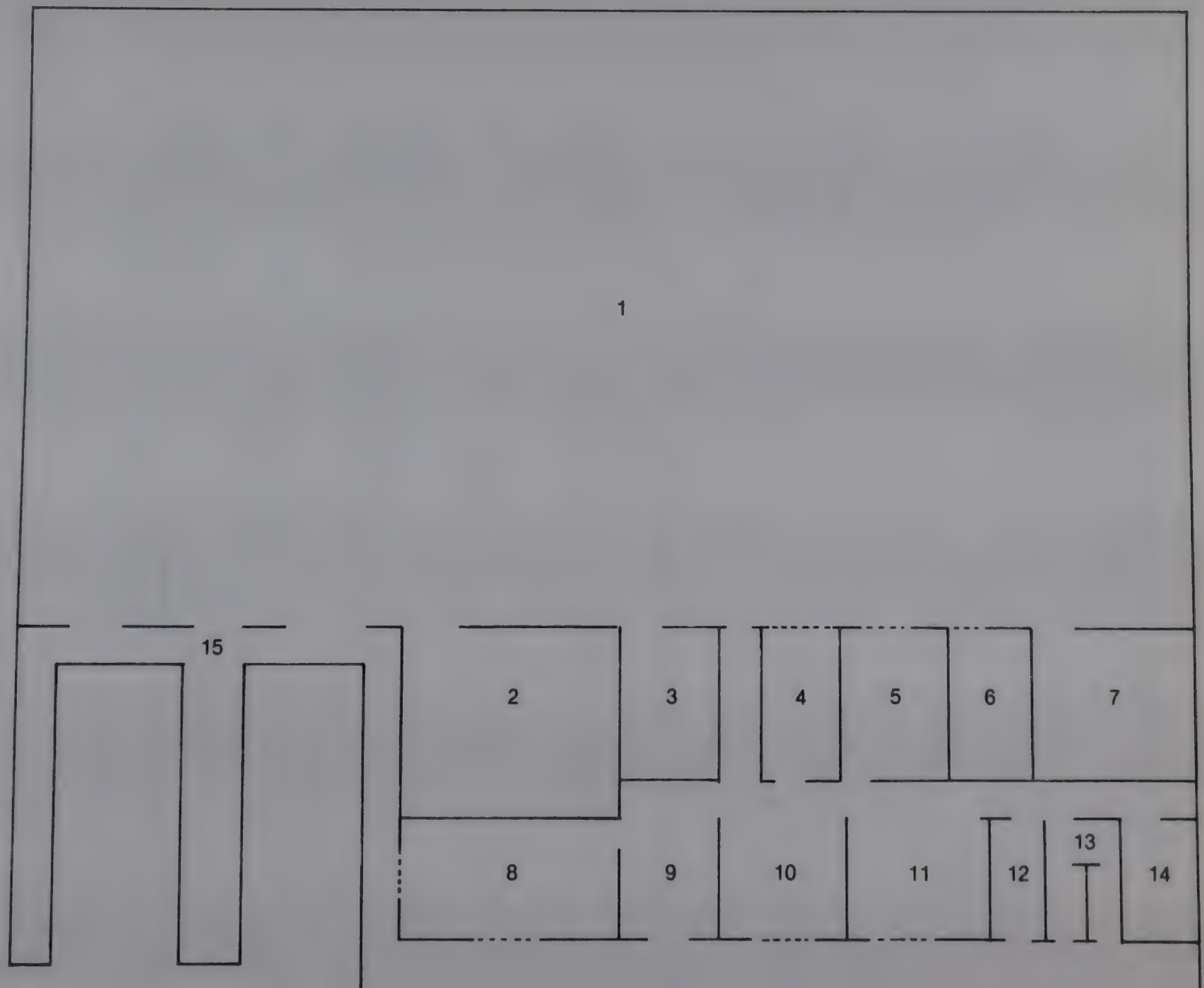
Checklist for Warehouse Design

- ☑ EASY MOVEMENT -- Use one-floor layouts. Interior partitioning limits stock arrangement; if partitions are used, position walls and doors to promote easy movement.
- ☑ GOOD CIRCULATION -- Use of fans and forced ventilation prolongs shelf-life and improves working conditions.
- ☑ BULK STORAGE ON PALLETS -- This improves efficiency of stock handling; pallets are cheaper to construct than shelves and hold more stock for the amount of space they occupy; they facilitate circulation and allow easier access to stock for cleaning.
- ☑ EASY MAINTENANCE -- Floors should be graded and drains placed to catch runoff; provide well-spaced faucets.
- ☑ SYSTEMATIC ARRANGEMENT OF STOCK -- Frequently used arrangements are by therapeutic/pharmacological class, clinical indications, level of service, and alphabetic sequence. Array stock in the same order that products appear on standard requisitions.
- ☑ COLD CHAIN MAINTAINED -- Vaccines require special cold storage arrangements. Cold rooms, refrigerators, and freezers should be protected from power cuts by backup generators.
- ☑ SECURE STORAGE AREA FOR CONTROLLED SUBSTANCES -- Narcotics must be stored in areas with restricted access.
- ☑ PROTECTED STORAGE AREA FOR FLAMMABLE SUBSTANCES -- Ether, alcohol, and fuels are best stored in out-buildings. Otherwise the storage room should seal tightly, be well ventilated, and be insulated with fireproof material.
- ☑ FIRE PREVENTION MEASURES -- Do not allow trash to accumulate; provide smoke alarms, fire extinguishers, and a night watchman.

Figure IV.D.6.

Sample Warehouse Layout

1 Main Storage Area
2 Repackaging
3 Cold Room
4 Warehouse Director
5 Procurement Office
6 Director of Supply (Logistics)
7 Flammable Substances
8 Shipping and Receiving
9 Reception Area
10 Records and Inventory Control
11 Stenography
12 Coffee Room
13 Toilets
14 Controlled Substances
15 Main Entrance and Loading Docks



too hot by noon for sustained work. Installation of fans will increase the length of the work day as well as improve storage conditions.

Proper positioning of shelving and use of pallets promotes both air circulation and movement of stock. Ample aisle space between rows allows room to push through carts when preparing shipments. Allowing two feet between shelf rows and walls usually assures adequate circulation. The use of pallets permits circulation from below and provides protection from flooding.

Buildings should also be designed to facilitate cleaning. Faucets positioned around the storage area provide easy access to water. Use of pallets permits floors to be hosed down and scrubbed off. And graded floors and well-located drains allow the water to run off.

Pallet Storage

For upper level warehouses, where supplies arrive in bulk, storage on pallets is generally more efficient than on shelves (Figure IV.D.7.): it limits the amount of unpacking for storage and repacking for delivery. Moreover, stock is more easily dusted off and cleaned than on shelves; pallets are cheaper to construct than shelves; and, for practical purposes, pallets hold more stock for the space they occupy. Crates can be opened and inspected on a random basis for damage in transit and short shipments. Each pallet holds only one product and the pallets are arranged systematically.

Pallets can be placed in the same order that products appear on standard Requisition/Issue Tickets. Preparing shipments then is a simple matter of moving up and down rows and taking supplies directly from their original containers. When necessary, workers can easily move loaded pallets with manually operated hydraulic trucks. Also, when stock rearrangement is necessary, it is much easier to move pallets than it is to move loose stock which has been placed on shelves.

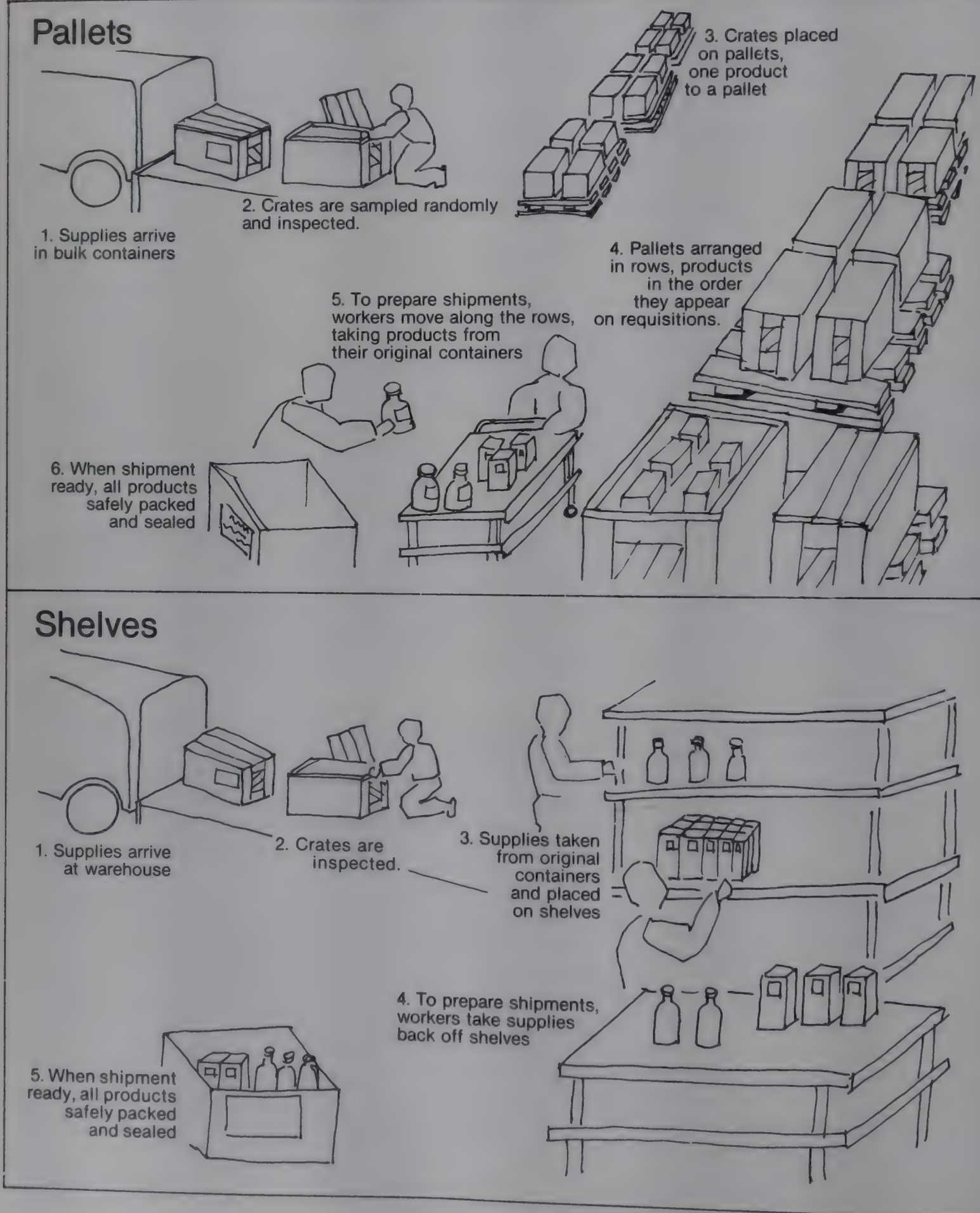
At lower level warehouses and clinical facility storerooms, shelving will predominate over pallets. These storage areas will primarily serve the facilities at which they are located and need not be set up for redistribution. In no case, however, should supplies be placed directly on floors; pallets or other forms of dunnage are a must if sufficient shelf space is not available.

Arrangement of Stock

Within warehouses and storerooms, drugs are arranged according to a specified organizational principle. Therapeutic/pharmacological class, clinical indication, alphabetic order, or level-of-use are commonly used (see Chapter II.A.). Within the warehouse itself as well as in clinical facilities, use of the therapeutic/pharmacological classification produces good results, perhaps because it provides a frame of reference within which workers can easily recognize individual products. (Figure II.A.4. provides a sample listing of therapeutic classes.) Level-of-use can be combined with this approach by using preprinted Requisition/Issue Tickets for each type of facility (see Figure IV.D.11. under the discussion of warehouse procedures in Section 3.a.). With this system, drugs are arranged in the warehouse by

Figure IV.D.7.

Pallet Versus Shelf Storage


Pallets
1. Supplies arrive in bulk containers
2. Crates are sampled randomly and inspected.
3. Crates placed on pallets, one product to a pallet
4. Pallets arranged in rows, products in the order they appear on requisitions.
5. To prepare shipments, workers move along the rows, taking products from their original containers
6. When shipment ready, all products safely packed and sealed
Shelves
1. Supplies arrive at warehouse
2. Crates are inspected.
3. Supplies taken from original containers and placed on shelves
4. To prepare shipments, workers take supplies back off shelves
5. When shipment ready, all products safely packed and sealed

their classes in the same order as they appear on the Requisition/Issue Ticket. Workers move along the rows of pallets packing only the type and quantity of drugs shown on the Ticket -- a greater range of products for hospitals, a lesser range for dispensaries. A final check before sealing the boxes assures that auxiliaries have not requested unauthorized drugs (e.g., morphine for backaches).

Special Storage Conditions

Some categories of supplies require special storage conditions. These include vaccines, narcotics, and combustibles. Vaccines require both refrigerators and freezers. Section 7 describes special cold chain requirements.

Narcotics and other controlled substances should be kept in secure locking rooms with only one entrance. The keys should be kept in a secure place, preferably a safe. Only the warehouse director and one other person should have access to them. (Chapter VI.C. describes security measures in greater detail.)

Combustibles such as alcohol, ether, and fuels must be stored in special rooms. A small, separate out-building is preferable since it virtually guarantees that fire will not spread throughout the warehouse. If a special building is not available, the room used to store these supplies must be fireproof and well-ventilated.

Fire Prevention

Accumulation of flammable trash, such as cartons and boxes, must not occur. Smoke alarms are inexpensive to install and provide warning in case fire does break out. For fire extinguishing, sprinkler systems are most effective. Their principal drawback is that if accidently set off they may ruin some stock. A cheaper alternative is to place extinguishers suitable for chemical fires at frequent intervals throughout storage areas, although they offer no protection unless someone is around to use them. Employing night watchmen serves the dual purpose of responding to fire alarms and protecting against theft.

Warehouse Size

A final factor to consider is that each descending level of the storage and delivery hierarchy should contain enough space to serve the one below it. To illustrate, it is easiest to begin at the bottom. The average offtake of all clinical facilities for a given delivery interval will determine the volume to be delivered down through the system. Assume that 200 clinical facilities consume a total of 1,000 m^3 during a three month interval, and that they are served by few district warehouses. Each of these must be capable of holding an average of 250 m^3 apiece plus room for safety stock; the central warehouse must hold at least 1,000 m^3 plus safety stock.

The alternative is for the central level to attempt to pass the large volume of supplies required at the clinical level through a small volume intermediate warehouse. This means that this warehouse must be brought up to

maximum stock level more than once for each delivery interval. This, in time, creates transport scheduling problems from both above and below, increases the possibility of stockouts, and bunches up the receiving, inventory control, and shipping procedures.

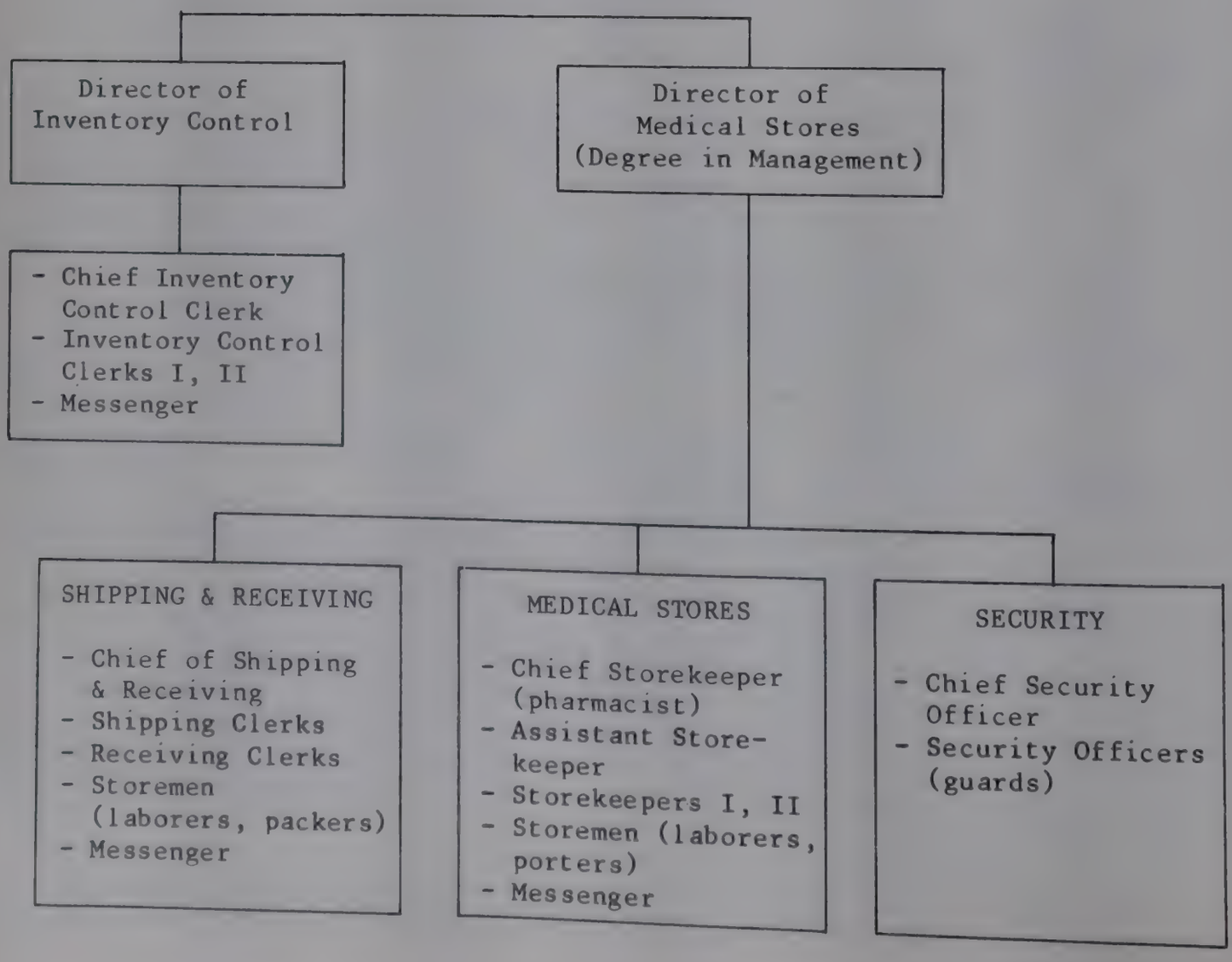
3. WAREHOUSE STAFFING AND PROCEDURES

This section considers the staff and tasks necessary to safely receive, store, and deliver supplies. Discussion focuses on the activities at an upper-level warehouse, and, though generalizable, it necessarily omits a number of possible refinements that can be built in according to need.

The basic staffing requirements of a pharmaceutical warehouse are presented in an organogram in Figure IV.D.8. These personnel carry out a series of activities in managing supplies which are, in practice, frequently haphazard

Figure IV.D.8.

Staffing Pattern for a Pharmaceutical Warehouse



and unnecessarily cumbersome. In this section a basic set of procedures is outlined to help clarify and simplify these activities.

A necessary accompaniment to these procedures, for efficient management of supplies within a warehouse, is a certain amount of paperwork and record-keeping. There are two objectives of this:

(1) To provide information on consumption and inventory levels for purposes of management decision-making, and

(2) To document the safe storage and movement of supplies. This provides an "audit trail" to trace the flow of drugs through the system and to identify points of loss and waste.

Several forms are required to achieve these objectives. They include the Invoice, the Receiving Report (Appendix IV.D.2.), the Requisition/Issue Ticket (Appendix IV.D.3.), the Stock Record Card (Figure IV.B.4.in Chapter IV.B.), the Bin Card (Appendix IV.D.4.), and the Delivery Voucher (Appendix IV.D.5.).

The movement of supplies and forms within a warehouse is shown in a flow chart in Figure IV.D.9. The basic procedures are described below. It is convenient to divide them into groups as follows: Receiving and Storage, Issuing, Shipping, and Inventory Taking.

a. Receiving and Storage

(1) When supplies arrive, receiving clerks inspect bulk containers for adherence to contract requirements, and for short shipments. When necessary, they annotate the Invoice, recording losses. They return one copy and send all others to the Inventory Control Unit. They also prepare two copies of the Receiving Report on the basis of the invoice. This document specifies the types, quantities, and conditions of the supplies received. They file one copy of the Receiving Report and turn the others over to a representative of the Medical Stores when he comes to pick up the supplies.

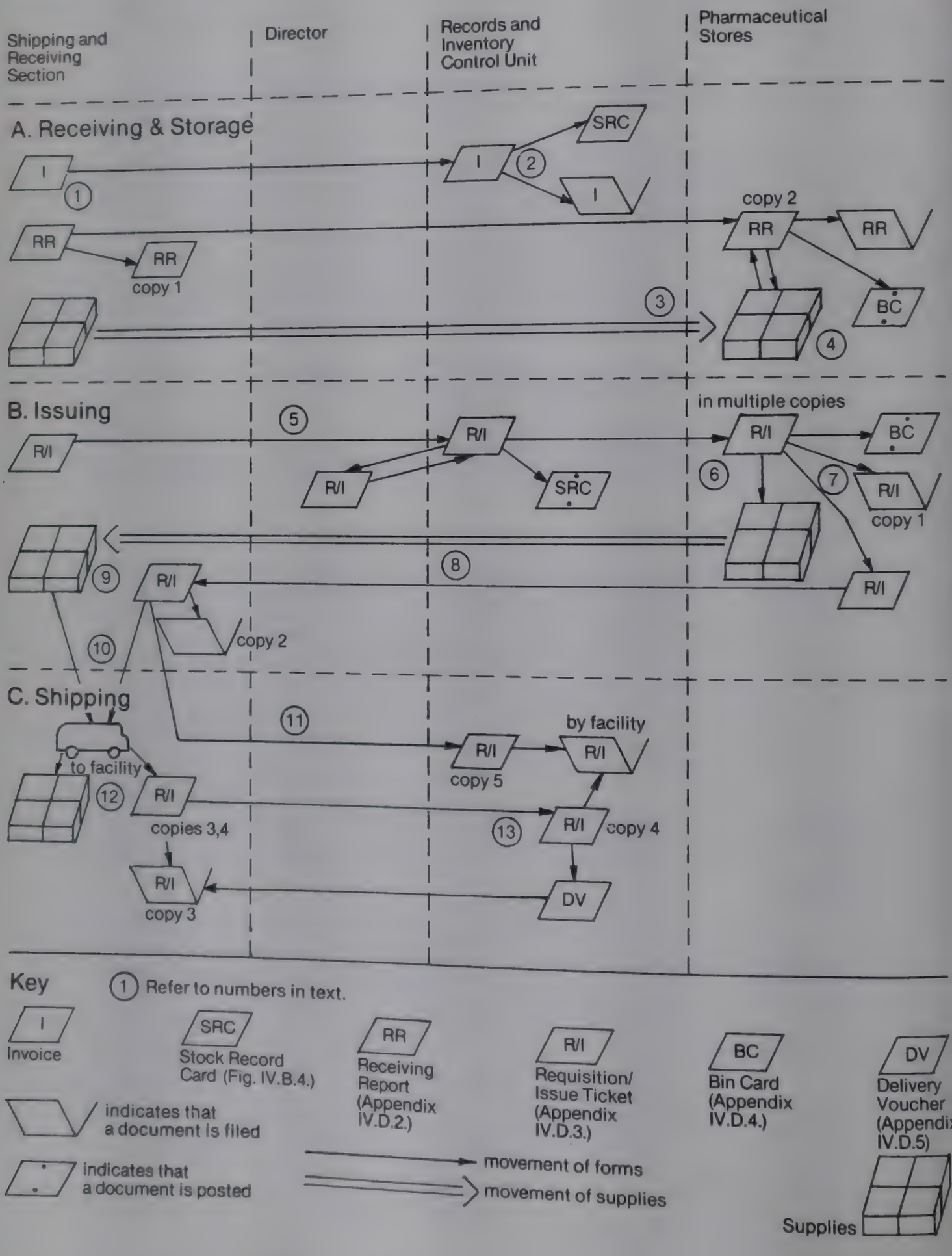
Figure IV.D.10. provides a sample checklist for inspecting drug receipts. By conscientious inspection of shipments, receiving clerks can form a critical part of the quality assurance program (Chapter III.D.).

(2) At the Inventory Control Unit, clerks use the Invoice to enter the quantities of new supplies received on Stock Record Cards and change the balance. They then file the Invoice. The purpose of Stock Record Cards is to provide a continuous record of the amounts of each supply remaining in stock.

Stock Record Cards and/or Bin Cards may be used to monitor shelf-lives. If Stock Record Cards are used, they show the expiration date of each drug. Two lots of the same drug with different expiration dates would require different cards. Whenever a lot reaches six months to expiration, the stock clerks attach a red tag to the card. The section chief informs the Director so that special steps may be taken to use these drugs before they expire on the shelves.

Figure IV.D.9.

Movement of Supplies and Forms Within a Warehouse



The Stock Record Cards also show the specified reorder point for each product. When this level is reached, the Section Chief notifies the Director so that he may start requisition or procurement procedures. Actually, this technique in inventory control can be applied in different ways and is more appropriate for upper level warehouses than lower ones. (See Chapter IV.B.)

(3) A representative of the Medical Stores (usually the Assistant Storekeeper) goes to the Shipping and Receiving Section to take custody of the supplies. He checks them against the Receiving Report and then accompanies them to the storeroom. Once there, he supervises porters who place them on pallets or other appropriate places (shelves, cold storage units). He then posts the Bin Cards. These cards remain with each lot of supplies and show issues, receipts, and balances -- the same information found on Stock Record Cards. Their purpose is to provide an easy reference on stock levels within the storeroom. Like the Stock Record Cards, they show expiration dates. After posting the Bin Cards, the Assistant Storekeeper files the Receiving Reports.

(4) Two ongoing activities of considerable importance are cleaning and stock surveillance. There should be enough unskilled labor available in warehouses to permit scheduled cleaning at least two or three times a week. In addition, the Assistant Storekeeper must ensure that storeroom employees inspect pallets and shelves daily for signs of pilferage or damage due to pests or water, or deterioration due to climatic factors. If a worker observes such signs, he notifies the Assistant Storekeeper. Storekeepers open suspect containers; the Assistant Storekeeper authorizes disposal of unsalvageable supplies and posts the Bin Card. He notifies both the Director and the Inventory Control Unit in writing of these actions. The stock clerks make appropriate entries in the Stock Record Cards.

Issuing

(5) When Requisition/Issue Tickets (R/I) arrive, shipping clerks review them to see that the types and quantities of supplies correspond to the needs of the warehouse or clinical facility requesting them. The clerks initial approval and send the R/I to the Inventory Control Unit. There, stock clerks review the availability of the supplies requested. They note any low inventory levels and send the R/I to the Director. The Director reviews the document, taking into account the stock clerks' notations. He may delete items, modify quantities, or approve the R/I as it is. He then returns the document to the Inventory Control Unit. There, the clerks post the Stock Record Cards and send all copies of the R/I to the Pharmaceutical storeroom. Eventually, when Shipping and Receiving provides a signed copy of the R/I verifying that the shipment has been made, the stock clerks change the pencil entries to ink.

(6) The Chief Storekeeper supervises preparation of shipments. As a clinical pharmacist, he is the only person authorized to make substitutions. Within the storeroom, supplies are arranged in the order that they appear on the Requisition/Issue Ticket. The storemen loose-pack

supplies in cartons. When issuing drugs, an important principle is to issue those drugs with the nearest expiration date first. The Assistant Storekeeper is responsible for this and for posting the Bin Card.

Figure IV.D.10.

Inspection Checklist for Drug Receipts

All Shipments -- Compare physical stock with supplier's invoice and original purchase order/contract. Note discrepancies on the Receiving Report.

- Number of containers delivered.
- Number of packages in each container.
- Visible evidence of damages (describe).
- Quantity in each package.
- Correct drug (don't confuse generic name and brand name), dosage form (tablet, liquid, etc.), dose (milligrams, % concentration, etc.).
- Take a sample for testing (if pre-acceptance sampling done, see Chapter III.D.).
- Presence of unique identifiers if required (Ministry of Health stamp, etc. -- see Chapter VI.C.).

Tablets -- For each shipment, tablets of the same drug and dose should be consistent. The following characteristics should be checked:

- Identical size, shape, color (shade of color may vary from batch to batch).
- Markings (scoring, lettering, etc.) should be identical on all tablets.
- No evidence of spots, pits, chips, breaks, uneven edges, cracks, embedded or adherent foreign matter, stickiness.
- No odor upon opening a sealed bottle (except flavored tablets and those with active ingredients normally having a characteristic odor) and no odor after being exposed to room air for 20-30 minutes.

Capsules -- Capsules should be inspected for the same characteristics as tablets. In addition, the following should be checked:

- No evidence of holes in the capsule.
- No empty capsules.
- No open or broken capsules.

Parenterals (Injectables) -- All products for injection (I.V. liquids, ampules, dry solids for reconstitution, suspensions for injection, etc.) should be checked for the following:

- Clarity of solution (solutions should be free from undissolved particles, within permitted limits).
- Dry solids intended for use in injections should be entirely free from visible foreign particles.
- Evidence of leakage from the immediate container (bottle, ampule, etc.).

(7) Figure IV.D.11. illustrates a pre-printed Requisition/Issue Ticket which facilitates the issuing process. Products are ordered by therapeutic class. Because each type of facility has its own pre-printed form, order by level-of-use is implicitly included. This single document serves not only as a requisition and issue ticket, but also as a stock report, as a source of consumption information for planning purposes, and as an indication of clinical activity for supervision and evaluation purposes.

(8) The Assistant Storekeeper takes all copies of the R/I and escorts the supplies to the Shipping and Receiving Section. A Shipping Clerk verifies that the shipment is complete and acknowledges receipt by signing on the appropriate line. The Assistant Storekeeper retains his copy for filing in the storeroom. The other copies remain at Shipping and Receiving for distribution.

c. Shipping

(9) At Shipping and Receiving, Shipping Clerks supervise the final packing, sealing, and labeling of the boxes. The Drivers (or other custodians) observe these procedures.

(10) The Shipping Clerks turn the packed supplies over to the drivers, also with 2 copies of the R/I for each shipment. The driver signs to acknowledge receipt of the shipment.

(11) There are two remaining R/Is. The Shipping and Receiving Section retains one and gives the other to the Inventory Control Unit, where it is filed by facility. In addition, they maintain a Cumulative Off-take Ledger for all pharmaceuticals. This ledger summarizes information on consumption in different formats for planning purposes. Using the R/I files as a data base, stock clerks make quarterly tabulations of overall consumption, consumption by individual facilities, by level of service, and by region. The Director of Inventory Control, who is an inventory control specialist, supervises this activity and is responsible for distributing this information to appropriate ministry divisions who require it for planning, evaluation, and supervisory purposes.

(12) Drivers deliver each shipment to the appropriate facility. Upon arrival, drivers and recipients count and inspect the supplies. They make notations in case of loss or damage in transit. Recipients sign both copies of the R/I, retaining one and returning the other to the driver.

(13) Finally, the drivers return their copies of the R/I to the Inventory Control Unit. There, Stock Clerks compare this final copy with the one they already have and file them together. If there are no abnormal discrepancies, the Inventory Control Clerks provide the drivers with a Delivery Voucher (Appendix IV.D.5.). This document certifies that drivers have safely delivered the supplies and are relieved of all further responsibility for them. If the clerks do find unexplainable losses, they send both copies of the R/I to the Director, who investigates the discrepancy and takes appropriate follow-up action.

Figure IV.D.11.

Sample Pre-Printed Requisition/Issue Ticket

REQUISITION/ISSUE TICKET

MINISTRY OF HEALTH

Department of Medical Supply

Requisition No. _____

Health Facility _____

Authorized by _____

Date _____

Status of Requisition:

- ☐ Regular
- ☐ Interim
- ☐ Emergency

Supply Period _____ to _____

ITEM No.	Stock Number 1	Description 2	Unit of Issue 3	Stock on Hand 4	Quantity Requested 5	Quantity Approved 6	Quantity Issued 7	Amount $ 8	Notes 9
		ANALGESICS							
1		Aspirin 350 mg. tablet	Packet						
		Anti-Allergics							
2		Diphenhydramine 25 mg. tablet	Packet						
		Antibiotics							
3		Benzathine Penicillin injectable 2,400,000 IU/5cc	Packet						
4		Penicillin, oral 250 mg. tablet	Packet						
5		Chloramphenicol 250 mg. capsule	Packet						
6		Triple sulfa 500 mg. tablet	Packet						
		Opthalmological Preparations							
29		Silver Nitrate	ampule						
30		Sulfacetamide solution	bottle 15cc						
		Vitamins & Minerals							
41		Multivitamins tablet	Packet						

Clearances:

1. _____ Shipping & Receiving Review
2. _____ Director of Medical Stores
3. _____ Inventory Control Unit
4. _____ Medical Stores
5. _____ Shipping & Receiving
6. _____ Driver or Custodian Accepts Shipment
7. _____ Recipient, Acknowledgement of Receipt of Shipment

_____ Hour and Date Received

d. Inventory Taking

The Stock Record Cards and the Bin Cards provide a continuous record of the amount of each supply item in stock. When the supply of any item falls below a certain specified level, that item is reordered by Inventory Control Clerks, using the Stock Replenishment Request Form (see Appendix IV.D.1.), which is submitted to the central Procurement Office.

The Inventory Control Unit must periodically verify that the information shown on the Stock Record Cards and Bin Cards is correct. This requires actually counting the numbers of items present and comparing the results with the numbers indicated on the Stock Record Cards. Inventory taking should accomplish several purposes (United Nations, 1978), including:

- to help enforce regulations and procedures designed to prevent loss and waste;
- to serve as a check for the adequacy of security measures;
- to provide an additional form of evaluation which may uncover defects in the warehouse system;
- to promote periodic evaluation of storage conditions and the adequacy of storage facilities, layout, and stock arrangement; and
- to identify surplus, expired, and obsolete stock.

The physical inventory (stock-take, stock verification, audit) is most commonly done on an annual basis. Business stops for a few days while Stock Clerks and Storekeepers count all supply items, identify discrepancies, and reconcile the Stock Record Cards. When significant discrepancies do occur, the Invoices, Receiving Reports, and Requisition/Issue Tickets provide an audit trail to identify clerical error or help establish the point in the process at which supplies disappeared.

An alternative approach to annual inventory taking is to take monthly physical inventories on portions of the total stock. The procedure is the same, but the quantity of supplies checked at each inventory taking is smaller. One advantage to this approach is that it provides for continuous physical inspection within the storeroom, promoting both security and an awareness of storage conditions. If the annual inventory approach is used, it is a good idea to perform frequent random spot checks throughout the year to display a continuous concern for security.

. PROMOTING EFFICIENCY WITHIN WAREHOUSES

As suggested in the introduction, the tasks associated with storage and delivery often enjoy little esteem in public health systems. The normal by-product of this perception is low pay, poor working conditions, low motivation, and their cumulative result: low performance. A discussion of socio-economic factors influencing these conditions is tempting. This section confines itself, however, to specific suggestions for promoting efficiency.

a. Working Conditions

Adequate ventilation -- This was mentioned as an important factor in warehouse design, but is equally important for good working conditions.

Cleanliness -- Dust and accumulation of trash contribute to the drabness of facilities that are not renowned for their aesthetic appeal. As suggested, most warehouses have ample personnel available for scheduled clean-ups. Of course, adequate equipment must be available.

Sanitary Facilities -- Where pharmaceuticals are stored and processed, clean and functional toilets and wash basins are essential.

Segregrated Rest Area -- This is less of a luxury than it seems. Upper level warehouses frequently have many porters, packers, and messengers who work intensively during some periods and have free time between jobs. It is better to have them resting in a set-aside area than in doorways and offices chatting with people who have steady work to do.

b. Written Materials

Operations Manual -- Each section should now have a copy of an operational manual that presents general policy and specific procedures and job description (as noted in Figure IV.D.12.). The manual should include comprehensible organograms and flow charts and any other visual aid that clarifies operations. These documents will normally be used only by the Director and Section Chiefs to settle normative and procedural questions.

Job Descriptions -- Most jobs in warehouses are relatively non-technical, and so their descriptions will be brief. Display placards that present essential points of the descriptions in work areas. In addition, present each worker with a personal copy. Porters, packers, and messengers are often illiterate; they should nonetheless be provided with written job descriptions. Contents of the documents should be explained in group presentations.

Posted Information -- Large signs indicating "no smoking" (symbolically, if necessary) and restricted areas should be posted where applicable. Signs indicating the categories of stock in rows of shelves and pallets will facilitate location of stock.

c. Supervision

Take pains to clarify the supervisory hierarchy for all workers. Major personnel problems can be preempted by solving minor ones at their appropriate level. Persons who will not accept delegated supervisory responsibilities are not good candidates for section chiefs, as supervision or spot checking of each worker by section chiefs should be performed regularly. Positive feedback, when warranted, is essential. Minor lapses should be kept in perspective, and more major ones, such as proven cases of theft or reckless driving, handled promptly through established ministry regulations.

Figure IV.D.12.

Contents of a Warehousing System Manual

- Statement of Operational Policy
- Organizational Staffing Pattern
  - . Central Level
  - . Regional Level
  - . District Level
  - . Community Level
- Lines of Authority
- Overview of the sequence of tasks and activities in the materials management process with discussion of the objectives of the process
- Job Descriptions -- all personnel by level, each level treated separately
- Personnel Regulations
- Logistics Information System
  - . Flow chart of Central, Regional, and District Information Flow
  - . Warehouse Operations Forms -- Invoice, Receiving Report, Requisition/Issue Ticket, Stock Record Card, Bin Card, Delivery Voucher
- Accounting System and Procedures
- Inventory Control System and Procedures
- Security System and Regulations
- Warehouse Administration
  - . Operating Budget (Utilities, Salaries, Maintenance, Supplies, Miscellaneous)
  - . Maintenance Procedures (for buildings and equipment)
- Special Operating Instructions
  - . Cold Chain Storage Procedures
  - . Quality Control Procedures
- Shipping/Packaging Procedures

d. Training

Each worker should receive an appropriate amount of formal training in his job. Both the manual and job descriptions provide useful quick references to the tasks that should be performed. The non-technical nature of most jobs

in the warehouse suggests that follow-up supervision, not long classroom sessions, is more likely to produce results. Supervision should be regarded as part of a long-term training process, not simply the act of assigning tasks and reacting to lapses.

5. STORAGE AND STOCK CONTROL AT CLINICAL FACILITIES

The basic characteristics of good storage space at clinical facilities are the same as for warehouses. Storerooms require ready access, good circulation, dryness, and security. In most cases, the smaller quantities of drugs stored will permit use of shelving. As in the warehouses, products are arranged in therapeutic groups and in the order they appear on requisitions. Large labels placed on the shelves with each product facilitate recognition.

The Storekeeper and Assistant Storekeeper alone have access to the storeroom. A "Dutch Door" arrangement in which the top half of the door opens, while the bottom remains closed, keeps out unauthorized persons and permits easy communication. Keys should be limited to one member of the warehouse staff and the director of the facility.

At lower level facilities such as rural health posts, clinical personnel frequently perform all supply management activities. It is seldom the case, however, that medical auxiliaries or community-based workers receive specific training for this. The result is that the quality of supply handling and storage conditions deteriorates as one moves to the periphery of the delivery system.

Training programs for clinical personnel who will handle supplies should include specific courses of instruction in the following subjects:

- Setting up a storeroom and good storage practices;
- Use of stock control forms including requisitions, stock records, and prescriptions; and
- Cold chain procedures, including the use and preventive maintenance of refrigerators.

Stock control procedures should be kept as simple as the situation allows. The main determinant is average daily level of service -- the number of patients seen and/or the number of prescriptions filled. In small facilities such as health posts, where the number of prescriptions seldom exceeds 50 a day, dispensing can be done directly from the storeroom, which doubles as a pharmacy. The forms required are a Prescription Slip, a Pharmacy/Clinic Stock Record (Figure IV.B.8. in Chapter IV.B.), and a Requisition/Issue Ticket. Procedures will vary with the training of the health workers and needs of the system. The following is one method of stock control:

(1) Auxiliaries see patients. When medication is required, they fill out a separate prescription slip for each medicine. A patient may receive more than one medicine, hence more than one prescription.

(2) The auxiliaries go the storage shelves, take down the required medicines, and place the prescriptions in a prescription box.

(3) At the end of each day, auxiliaries sort the prescriptions by type of drug and enter the total amount of each drug issued on the individual drug stock records.

(4) When it is time to order supplies, auxiliaries use the stock record to fill out the requisition. Normally they will order the quantity of each supply dispensed since the last delivery, that is, enough to bring stocks up to a predetermined maximum level. (See Chapter IV.B.).

(5) When stocks dip below their minimum level before a scheduled delivery, or when emergency supplies are needed, they prepare and forward an interim requisition. The regular Requisition/Issue Ticket can be used for this prupose.

Larger facilities will require a separate pharmacy and storeroom arrangement. This adds a step to the stock control routine, but it simplifies operations when a facility fills a large number of prescriptions daily or has more than one pharmacy or specialized outlet (operating room, inpatient wards). The added step does not greatly complicate matters. For example:

(1) Clinical personnel see patients and fill out prescription slips.

(2) Patients or staff members take the prescription to the pharmacy. The Pharmacist (or Dispenser) issues medicines and drops the prescription in a prescription box.

(3) At the end of each day, the Pharmacist sorts the prescriptions, fills out an Internal Requisition (Appendix IV.D.7.), and takes it to the storeroom. For frequently dispensed products (aspirin, multivitamins, magnesium trisilicate), some systems keep daily consumption reports at the pharmacy level. The dispenser then simply requests the estimated requirement for the following day from the storeroom. Control is assured by requiring that each day's prescriptions be banded together and saved for a month. The Pharmacist continues to report consumption of expensive or physician-prescribed drugs.

(4) The Storekeeper issues supplies, posts the Stock Record, and files the Internal Requisition.

(5) At periodic intervals the storekeeper fills out the facility's Requisition/Issue Ticket and forwards it.

6. ESTABLISHING TYPES AND AMOUNTS OF DRUGS TO STOCK AT EACH LEVEL

Interest in drug formularies usually focuses on the products selected. Quite apart from the contents of the list is the question, "Which drugs should be stocked at which facilities?" The health services delivery system is a pyramid of facilities and personnel in which each lower level provides more

basic services and fewer specialized services. At the apex are large urban hospitals with sizable staffs of physicians, trained and equipped to provide specialized services. At the base of the pyramid are the community-based workers, trained to provide a few basic services within their own communities.

Moving down this hierarchy, the variety and sophistication of medicines available at each level diminishes. The level-of-use categories described in Chapter II.A. and illustrated in Appendix II.A.2. provide an extremely useful framework for managing drug distribution and, more specifically, for stocking peripheral facilities. If the categories are well-chosen and the supply system is responsive, clinical facilities that are heavily utilized will be well stocked with the drugs they are authorized to dispense.

The average level of stock at each facility should include the working stock and a reasonable safety stock. These quantities may be determined by trial-and-error or more systematically by the techniques described in Chapter II.B.

Understocking of peripheral facilities is the rule, rather than the exception, in many health systems. Scarcity of financial resources combined with an unwillingness to charge for publicly supplied medications contributes significantly to this understocking. Nevertheless, the impact of poor supply management practices at central, regional, and district levels should not be underestimated. Stockouts at the local level should not be attributed simply to lack of financial resources; such shortages are a reflection of the performance of the entire supply system, and eliminating such shortages may involve changes at all levels.

7. MAINTAINING THE COLD CHAIN

Preventable communicable diseases continue to be major causes of death, disability, and deformity, in part because of the inadequacy of cold chain distribution systems. The World Health Organization's Expanded Programme on Immunization (EPI) has developed a detailed operations manual and several training manuals for use in designing and implementing a dependable cold chain and immunization program. Figure IV.D.13. summarizes the requirements for an effective cold chain, the details of which should be sought in the EPI publications.

At central facilities and at other facilities storing large amounts of vaccine, cold rooms, refrigerators, and freezers should be backed up by auxiliar generators in case of power failures. The generators should be equipped to start automatically when power is cut. Fluctuation in ambient temperature can affect internal temperature of cold storage units. Accordingly, the temperature should be checked and recorded daily. External thermometers, built into the units, are ideal for this. This check can also be performed by placing thermometers inside the units. Figure IV.D.14. lists the temperature requirements for different vaccines.

At peripheral facilities, vaccines can be stored in cold storage units in the room in which they are administered. Thermometers are placed in freezers

Figure IV.D.13.

Requirements for a Dependable Cold Chain*

LEVEL	STAFF	SUPPLIES AND EQUIPMENT	MANAGEMENT (Procedures & Information System)
National/ Central Level	Immunization Program Manager Coordinating Committee Operations Officer • Central Storekeeper • Transport Manager • Finance Officer Evaluation Supervisor Chief Medical and Nursing Officers Trainers for Training Workshops (cold chain operations, immunization techniques, vehicle maintenance, management) Drivers, Mechanics	Vaccines Vaccine Control Laboratory (where feasible) Two-Temperature Cold Room, Freezers, Refrigerators Thermometers Standing Power System Cold Transport Boxes Vehicles (station wagons), Fuel Stationery, Forms	Program Planning • Demographic and Epide- • miologic Information • Administrative Structure • Logistic System Supply Distribution Control • Procurement • Storage • Delivery Supervision of Independent Evaluation Staff Recruitment and Training Collection and Compilation of Information • Costing Information • Vaccinations Provided • Disease Surveillance • Supplies Usage • Transport Data • Cold Chain Performance
Regional/ Provincial Level	Regional Immunization Operations Officer Regional Medical and Nursing Officers Evaluation Team Staff for Training Workshops Drivers, Merchants	Vaccines Top-Opening Refrigerators and Freezers Standby Fuel or Power Thermometers Cold Transport Boxes, Insulation Ice Vehicles (station wagons), Fuel Stationery, Forms	Supply Distribution Control Supervision of Field Operations Collection and Compilation of Information (daily temperature record usage of fuel, spare parts, breakdowns and maintenance) • Vehicle Logs, Vehicle • Maintenance and Repair, • Fuel and Oil Use • Cold Chain Performance • Vaccine Usage and Wastage
District/ Local Level	Center Supervisors Mobile Vaccination Team Leaders Vaccinators Advance Men Staff for Training Workshops	Vaccines Top-Opening Refrigerators Small Vacuum Flasks, Insulation Transport Boxes Ice Jet Injectors Syringes, Needles, Sterilizers Vehicles (4-wheel drive), Bicycles Stationery, Forms	Supply Control Operation of Vaccination Clinics Collection of Information (daily temperature record, usage of fuel, spare parts, breakdowns and maintenance) • Transport Records • Cold Chain Performance • Vaccination Reporting Forms

* Based on WHO, 1977.

Figure IV. D. 14.

Temperature Requirements for Vaccine Storage

VACCINE	Level:	Central	Regional	Local
	Storage Time:	6 to 18 months	3 months	1 month
Measles Oral Polio		-15°C to -25°C		
DPT* Tetanus* BCG			+4°C to +8°C	

*Never freeze DPT or tetanus

Source: WHO, EPI Manual, 1977.

and refrigerators. Internal temperatures are monitored daily. Taping temperature recording charts to refrigerator doors promotes this crucial activity (Appendix IV.D.6.).

In addition to adequate storage conditions, the distribution system must also have the necessary cold storage boxes for transport between facilities and to immunization sites. This, too, is covered in detail in the EPI publications.

SUMMARY

Adequate storage and regular delivery of drugs are imperative for the effective operation of public health programs but are frequently neglected.

Medical stores, or warehouses, should be positioned to promote the fastest and least expensive transport of supplies from source to user. Factors to consider include:

- location of supply sources
- number and location of clinical facilities
- transport links between sources and clinical facilities
- transshipment requirements
- seasonal factors that cut routes
- number, type, and capacity of existing storage facilities

Individual sites should be selected, considering access, drainage, security, water, and electrical and telephone service.

Warehouses should be designed to allow for easy movement of supplies, good circulation, bulk storage on pallets, easy maintenance, systematic arrangement of stock, cold storage areas, secure and protected storage areas, and fire prevention.

Staff are required to safely receive, store, and deliver supplies, according to specified procedures. The forms required include:

(1) Invoice
(2) Receiving Report
(3) Requisition/Issue Ticket
(4) Stock Record Card
(5) Bin Card
(6) Delivery Voucher
(7) Stock Replenishment Request

Efficiency within warehouses can be promoted via good working conditions; an operations manual, job descriptions, and posted information; and adequate training and supervision.

Stock control procedures at clinical facilities should be kept clear and simple. Stock items for each storage point should be systematically selected, preferably on the basis of level-of-use categories or a similar system.

An effective cold chain must be maintained throughout the distribution system. This requires acquisition and maintenance of specific refrigeration equipment, recruitment and training of specialized cold chain personnel, and institution of cold chain forms and procedures.

CHAPTER IV.D. REFERENCES

Attwood, P.R.: Planning a Distribution System. London: Gower Press Limited, 1971.

Bowersox, D.J.: Logistical Management. New York: Macmillan Publishing Co., Inc., 1974.

Davis, G.M. and Brown, S.W.: Logistics Management. Lexington, MA: D.C. Heath and Company, 1974.

Elford, J.: How to Look After a Refrigerator. London: AHRTAG, 1980.

Housley, C.E.: Hospital Material Management. Germantown, MD: Aspen Systems Corporation, 1978.

Intermediate Technology: A Manual on Building Construction. London: Intermediate Technology Publications Ltd., 1975.

Kurtzman, M.: Model for the Development of Rural Pharmaceutical Services. American Journal of Hospital Pharmacy 34: 163-167, 1977.

Lloyd, J.S.: Improving the Vaccine Cold Chain II; Progress Report December 1977. Geneva: World Health Organization, 1977.

McMahon, R. et al: On Being in Charge -- A Guide for Middle-Level Management in Primary Health Care. Geneva: World Health Organization, 1980.

Ministry of Public Health, Afghanistan: New Central Warehouse System and Regulations Concerning Issuing and Return of Goods. Boston, MA: Management Sciences for Health, 1974.

Quick, J.D.: Improving Pharmaceutical Supplies Management in Developing Countries: Impact of Selected Factors on Costs and Shortages. Unpublished Master's Thesis. 1979.

Taff, C.A.: Management of Physical Distribution and Transportation. Homewood, IL.: Richard D. Irwin, Inc., 1972.

United Nations: Supply Management: Towards Better Use of Equipment and Material Resources in Developing Countries. New York: United Nations Department of Economic and Social Affairs, ST/ESA/SER.E/16, 1978.

U.S. Department of Health, Education and Welfare: Planning for Hospital Pharmacies. Washington, D.C.: U.S. Government Printing Office, 1974.

World Health Organization: Expanded Programme in Immunizations, and EPI Training for Mid-Level Managers. Geneva: World Health Organization, EPI/G/77.1, 1977.

STOCK REPLENISHMENT REQUEST

MINISTRY OF HEALTH
Department of Medical Supply

Prepared by: _____ Inventory Control Clerk Date _____

Reviewed by: _____ Procurement Manager Date _____

Request No. _____

To Be Completed By Inventory Control Clerk at Re-Order Time										To Be Completed By Director of Procurement			
ITEM No	Stock Number 1	Description (include units) 2	Re-Order Level 3	Stock on Hand 4	Already on Order 5	Total Available (4 & 5) 6	Average Monthly Issues 7	Safety Stock 8	Quantity Requested 9	Estimated Unit Price 10	Estimated Total Cost 11	Quantity Approved for Order 12	Notes 13
1													
2													
3													
4													
5													
6													
7													
8													
9													
10													

Remarks:

Appendix IV.D.2.

Sample Receiving Report

MINISTRY OF HEALTH **RECEIVING REPORT** **Department of Medical Supply**

Report No. _____ Supplier _____

Date _____ Ship/Flight/Train _____

Invoice/ Number	Description	Unit	Condition	Quantity	Unit Price	Total Value	Comments

Delivered
Shipping and Receiving

Received
Medical Stores

Unpacked by _____

Checked by _____

ndix IV.D.3.

mple Requisition/Issue Ticket

REQUISITION/ISSUE TICKET

MINISTRY OF HEALTH

Department of Medical Supply

Requisition No. _____

Health Facility _____

Authorized by _____

Date _____

Status of Requisition:

- ☐ Regular
- ☐ Interim
- ☐ Emergency

Supply Period _____ to _____

Stock Number 1	Description 2	Unit of Issue 3	Stock on Hand 4	Quantity Requested 5	Quantity Approved 6	Quantity Issued 7	Amount $ 8	Notes 9

arances:

_____ 2. _____ 3. _____ 4. _____

Shipping & Receiving Review — Director of Medical Stores — Inventory Control Unit — Medical Stores

_____ _____ _____ _____

Shipping & Receiving — 6. Driver or Custodian Accepts Shipment — 7. Recipient, Acknowledgement of Receipt of Shipment — Hour and Date Received

Appendix IV.D.4.

Sample Bin Card

BIN CARD

MINISTRY OF HEALTH

Department of Medical Supply

Description _____ Unit of Issue _____

Stock No. _____ Expiration Date _____

Date	Document/ Number	Received From/ Issued To	Received	Issued	Balance	Ini- tials

ppendix IV.D.5.

ample Delivery Voucher

DELIVERY VOUCHER

MINISTRY OF HEALTH

Department of Medical Supply

This certifies that _____, official custodian of the shipments listed below, safely delivered all of the supplies for which he was responsible to the establishments specified below and on the dates indicated. Having performed his duty, he has no further legal responsibility for any of these materials.

lumber of equisition/Issue Ticket	Date Accepted	Establishment Delivered To	Date Delivered

mments

CAUTION: DO NOT LOSE THIS DOCUMENT

_____ _____

entory Control Warehouse Director

Sample Refrigerator Control Card

REFRIGERATOR CONTROL CARD

MINISTRY OF HEALTH

Department of Medical Supply

Refrigerator Make and Model: _____

Facility and Location: _____

Person Responsible for Making Daily Checks: _____

			1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Month:		Year:																															
Daily Temperature Checks																																	
All Refrigerators	Morning Reading																																
	Afternoon Reading																																
	Breakdowns	Hour Detected																															
		Temperature at Breakdown																															
		Refrigerator Repaired																															
Kerosene	Full Tank																																
	Number of Liters																																
	Wick and Exhaust Tube Cleaned																																
	New Wick																																
	New Glass Chimney																																
Gas	New Cylinder Installed																																
	Burner Cleaned																																

Adapted from WHO EPI Manual, 1977.

Appendix IV.D.7.

Sample Internal Requisition

MINISTRY OF HEALTH

INTERNAL REQUISITION

Department of Medical Supply

Facility _____

Number _____

Requesting Unit _____

Date of Last Request _____

Date of This Request _____

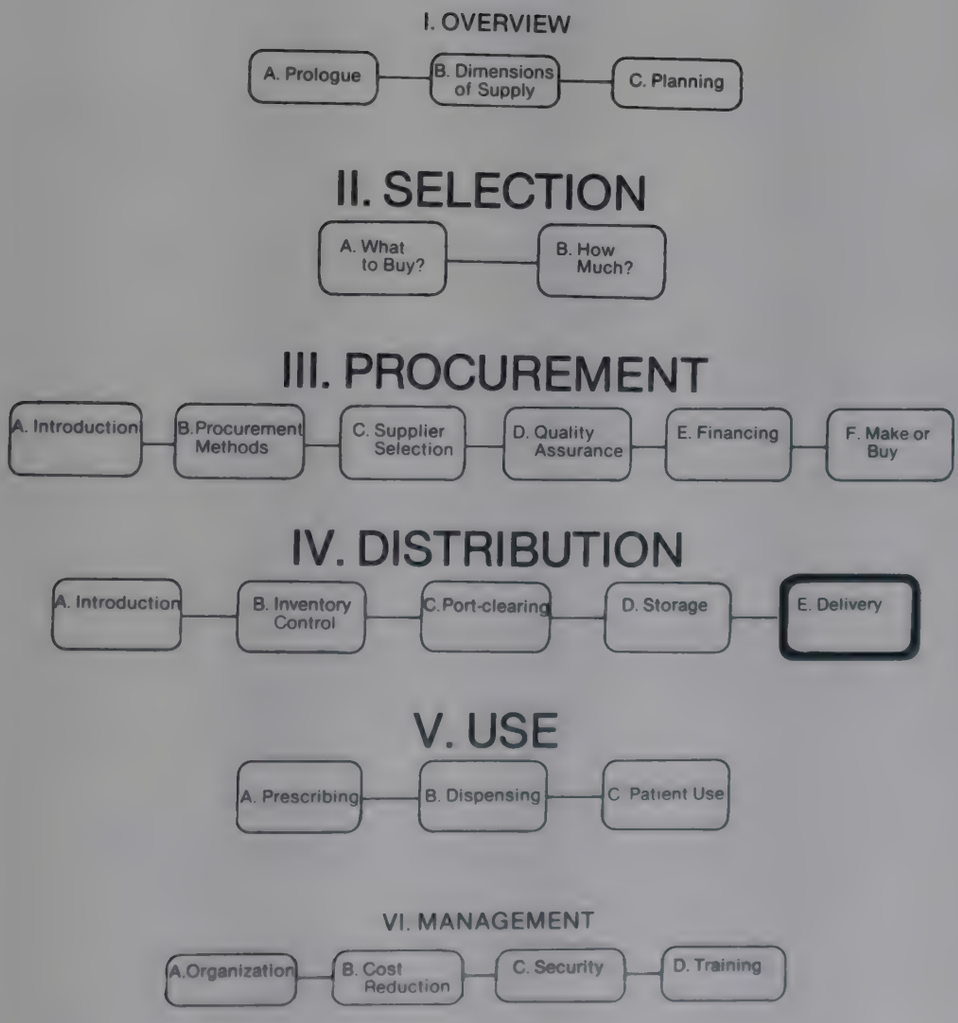
Item No.	Stock Number	Description	Unit	Amount Issued	Present Balance	Amount Requested	New Balance

_____ Requested by

_____ Storekeeper

Chapter IV.E.

Delivery Strategies



	Page
1. TRANSPORTATION PLANNING	379
a. Use of Ministry of Health Vehicles	380
b. Delivery Arrangements with Suppliers	382
c. Alternatives in the Public and Private Sector	382
d. Railways	383
e. Air Transportation	383
f. Inland Waterways	383
2. ACQUIRING AND MAINTAINING VEHICLES	384
a. Vehicle Selection	384
b. Preventive Maintenance	394
c. Driver Education	386
d. Repair Maintenance	386
e. Spare Parts	386
3. ESTABLISHING DELIVERY PATTERNS	387
a. Delivery Intervals and Stock Levels	387
b. Scheduling	388
c. Routing	391
SUMMARY	395
REFERENCES	396
APPENDIX	
IV.E.1. Vehicle Repair Tool Kit	397

Delivery Strategies

Delivery is frequently the least organized activity in the distribution process, and disruptions can occur at any or all levels of the system. Effective delivery thus requires careful planning and execution. The factors to consider include:

- Transport Selection
- Delivery Intervals and Stock Levels
- Schedules
- Routes.

In this section we will present suggestions and techniques which should make the earlier steps in the supply process positively felt at the clinical level. All of these early steps are unimportant if drugs are not delivered safely and on a timely basis to the ultimate users.

1. TRANSPORTATION PLANNING

Transportation planning begins with a thoughtful and creative analysis of the transport resources available (Figure IV.E.1.). Decision-makers often limit their thinking on transport to the vehicles available within the public health system, however disappointing the service from these vehicles may be. Fortunately, attractive alternatives are available. One may arrange with suppliers to deliver directly to warehouses and/or clinical facilities at various levels of the system. Established means of transport in the commercial sector or other branches of government may also be available. In addition, local charitable organizations may be able to provide transport to certain areas. It is through combinations of these and other alternatives that the greatest economy and flexibility can be obtained. Certainly, there is an element of complexity in this approach. Yet in practice, it is only a matter of selectively connecting resources that already exist. The costs and practical benefits of these alternatives will vary from country to country.

Comparing alternative transportation modes may be difficult. Available options can be considered in terms of the following factors:

(1) Transport cost, which is the freight charge in the case of commercial carriers. For government transport, it is the sum of vehicle acquisition costs, maintenance, fuel, and driver salaries;

(2) Transfer costs resulting from handling charges and expenses when goods are moved from one mode of transport to another;

(3) Cost of insurance to protect goods from damage, loss, or pilferage in transit;

Figure IV.E.1.

Transportation Options for Public Drug Supply

Highways

- Ministry of Health vehicles, including bicycles
- Vehicles from a central government motorpool or from other ministries (e.g., military)
- Delivery arrangements with suppliers
  Buses
- Commercial carriers
- Charitable organizations -- missionary groups, private aid programs

Railways

Air Transportation

- Commercial flights
- Government, including military, flights
- Private airplanes belonging to charitable and other organizations

Water Transportation

- Sea
- Inland waterways

(4) Port-handling charges which may be associated with the use of multiple seaports or interior airports;

(5) Packaging costs which may be incurred if special packaging is needed on certain types of transport;

(6) Transport reliability which will have a significant impact on costs if certain modes of transportation are associated with substantial delays, unpredictable delivery times, or excessive losses.

Transportation resources and the possibilities for linkages among various modes of transportation vary too greatly among countries to allow for specific transport recommendations. Therefore, the following paragraphs discuss some of the management implications of each of the major transport alternatives.

a. Use of Ministry of Health Vehicles

In theory, use of Ministry vehicles should provide centrally directed and responsive service. In countries with relatively few facilities to supply and where travel time and distances are not great, relying exclusively on minist transport may make the most sense. In countries where service requirements are extensive, however, and where storage and clinical facilities are widely

ASSESSMENT GUIDE IV.E.
Assessing Delivery Activities

- How would you evaluate the system's present performance with respect to delivery? How frequently are shortages or stockouts attributable to delays in delivery (rather than lack of adequate supplies at the central level)?

- To what extent do Ministry transport services support the pharmaceutical supply effort? Are appropriate vehicles reliably committed for scheduled deliveries?

- What trucking firms, railways, or airlines operate on routes that could serve Ministry warehouses? How do their rates and service compare?

- Which pharmaceutical distributors are most capable of meeting both Ministry supply requirements and making direct deliveries?

- At the present time, what are the relative contributions of these transport alternatives to the pharmaceutical supply effort? What are their relative costs for the volumes of supplies they move? What is the cost reduction potential with increased use of alternative means of delivery?

- What are the established delivery intervals at different levels of the system? How many standard items are presently out of stock? What is the frequency of interim requisitions? What items appear most frequently on them?

- What is known about delivery schedules and routines at regional or district levels? Which regions are thought to be most effective in meeting schedules? Are there special characteristics of their operations? In terms of preparing shipments? Route planning? Modes of transport employed?

- What information is available on expenditures for delivery on a region-by-region basis? Which regions are thought to have the lowest average cost per facility? What characteristics of their operations account for this?

dispersed, there will certainly be difficulties. Commonly observed problems include the following:

(1) Central Level Transport Sections are usually responsible for serving all of a ministry's divisions and their programs. A precondition to efficient transport management is current information on the upcoming transport needs of the division. Yet communication among these units is typically weak. Coordination is difficult and trucks often leave

half-filled with supplies for one program, when a brief wait would permit them to depart full, carrying materials for other programs that are destined for the same region. Even when Transport Directors do attempt to optimize the use of their vehicles, a number of other obstacles remain. Within the organizational context of many ministries, the most effective approach would be to assign vehicles directly to warehouses exclusively for their deliveries.

(2) Usually a high percentage of vehicles are deadlined due to lack of maintenance or because of accidents. They are on the inventory but not useable.

(3) Fuel is usually in short supply, making deliveries difficult, even when serviceable vehicles are available. A question of priorities enters here, too. When high-ranking personnel are assigned vehicles and given fuel allowances, fuel to support health services delivery becomes even more scarce.

(4) Vehicles are often donated or procured without regard to their operating costs or intended use. It is common to see 8-cylinder vehicles where 4-cylinder would be adequate, or to see expensive 4-wheel vehicles used exclusively on paved roads.

b. Delivery Arrangements with Suppliers

An alternative to using Ministry vehicles for delivery is to write contracts that oblige pharmaceutical suppliers to deliver to selected warehouses and clinic facilities (principally large hospitals). As requisitions pass up through the system, central level officials consolidate them and arrange purchases from suppliers who deliver direct from their own storage facilities. Where applied, this shifts part of the storage and transport costs to the suppliers. The most likely result of this type of arrangement is "two stage" delivery: suppliers deliver to selected hospitals and warehouses, and regional or district officials will make transport arrangements to peripheral facilities.

c. Alternatives in the Public and Private Sector

This manual assumes that the pharmaceutical supply program is centralized within the Ministry. This does not, however, mean that transport must be internally managed. Given the problems of procuring, maintaining, and fueling fleets of vehicles, there is much to be said for utilizing transport alternatives within other public agencies and the private sector. Other ministries that regularly travel rural routes, agriculture, for example, may have space available to handle medical supplies. Existing trucking, railway, and air services can also be taken advantage of. Where the situation warrants it, custodians may accompany supplies to guarantee safe delivery. Again, the local administrators assume responsibility from the main routes to peripheral areas. This, too, may involve the use of commercial transport.

d. Railways

Rail transport is highly suitable for certain transportation needs, especially the movement of large quantities of supplies from a seaport to an inland central medical store or from the central medical stores to large regional stores. Rail transport makes economical use of fuel, thus lowering freight costs. It is also the best suited to handling bulky packaging such as containers and pallets. Transshipment of bulk quantities of containerized drug shipments or shipments of drugs in their original containers on pallets can reduce both handling costs and pilferage losses. In addition, if railways are reliable, transshipment of bulk quantities may reduce the lead times for inland supply depots.

The main disadvantages of railways are that (1) they are hard to maintain and may therefore be unreliable, (2) delivery to the ultimate destination may still require transfer to trucks, and (3) suitable supply-handling equipment may not be available at inland stations to allow the use of containers or pallets.

e. Air Transportation

In certain areas air transportation represents the only feasible means of delivering supplies. But in most countries, transportation by air is not used regularly; rather it is for emergency deliveries and for delivery of special items, such as vaccines. It may be useful to maintain an inventory of existing scheduled flights, charter airlines, and potential mission pilots and flights. Although air freight charges are usually high, packaging costs are frequently lower and pilferage is often less than with land transport. In addition, the speed of air transport may entail savings through more efficient use of costly medications and reduced need for special cold storage facilities for vaccines.

Whenever air transportation is used, the availability of transport and necessary fuel at the receiving airport must be assured. In addition, the receiving airport must have suitable storage facilities, including cold storage, if necessary.

f. Inland Waterways

As with air transportation, inland navigation sometimes represents the only feasible delivery route to a particular area of the country. Where routes are well-established, freight charges are generally low compared with other modes of transport. Like rail transport, water transport can handle large volumes of supplies, although there may be less flexibility in terms of container and pallet storage. The difficulties with water transportation are that it is often quite slow; it is subject to lengthy delays, particularly if inland ports are congested or inefficiently operated; goods are frequently lost or damaged when their collection from the port area is delayed; and supplies are more vulnerable to damage or loss from bad weather, shipwrecks, and other mishaps. Seasonal variations may drastically limit accessibility by water. (In the Indonesian Archipelago, for instance, there are certain islands

which can be reached only two or three times during the year, since navigation is impossible during the transgression periods.) Thus, it is advantageous to have an alternative mode of transportation whenever water transport is planned.

2. ACQUIRING AND MAINTAINING VEHICLES

Vehicles are among the public health system's most expensive expendable supplies. The tendency in many countries is to drive them until they stop, then garage them. As mechanics cannibalize deadlined vehicles for parts, the results are fleets of continually diminishing size. (Actually, this would be a blessing in disguise given the rising costs of fuel, but there is usually some donor hanging around anxious to replace one deadlined Toyota with two 8-cylinder, air-conditioned GMC Carryalls.) Over the years, assistance programs have made little visible progress in establishing self-sustaining vehicle maintenance programs. There are five basic issues to consider for maintaining a fleet of operating vehicles.

a. Vehicle Selection

In many health programs vehicular transport is limited more by the lack of spare parts and mechanical expertise than it is by the actual number of vehicles owned. In other words, there are enough vehicles, if only they could be kept running. Thus, the ability to maintain a vehicle must be weighed very heavily in the selection of new vehicles. The offer of a donated vehicle may prove costly if the offer does not include provisions for spare parts or if the mechanics available on the vehicle's intended supply routes are not familiar with its repair and maintenance.

Thus, in choosing vehicles it is important to consider which vehicle models are used in the regions to be covered by the program, and therefore, which vehicles can most readily be repaired by service stations and mechanics along the supply routes. Suitability of existing repair services is particularly important in small programs or in new programs which have not yet developed their own vehicle maintenance services.

In selecting vehicles, the future availability of spare parts is also important. The willingness and demonstrated ability of local dealers to maintain stocks of spare parts should be considered. Expected future local sales of the vehicle under consideration is also of interest; expected sales growth makes the availability of parts and services more likely.

b. Preventive Maintenance

Each higher level of maintenance costs more than the one below. The purpose of preventive maintenance is to minimize the need for later repairs. Preventive maintenance is performed by vehicle operators with low cost materials such as crank case oil, water for radiators, and air for tires. Drivers should be required to perform preventive maintenance daily and to fill out checklists (Figure IV.E.2.).

DAILY PREVENTIVE MAINTENANCE RECORD

MINISTRY OF HEALTH
Department of Medical Supply

Vehicle Number:_____ Location: _____

Vehicle Make and Model: _____ Responsible Driver(s)/Mechanic(s):_____

Month: 19 Day:	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
1. Fuel																															
2. Engine Oil																															
3. Coolant																															
4. Coolant Leaks																															
5. Battery																															
6. Fan Belts																															
7. Engine Oil Leaks																															
8. Tire Pressure																															
9. Tire Condition																															
10. Brakes																															
11. Clutch																															
12. Temperature Gauge																															
13. Oil Pressure Gauge																															
14. Generator Charge																															
15. Lights																															
16. Tools																															
17. Repair Maintenance																															
18. Accident																															

Figure IV.E.2.
Daily Preventive Maintenance Record

c. Driver Education

This is an extension of preventive maintenance. Accidents or abuse of vehicles account for a sizeable portion of losses. Qualified instructors should train all drivers, test them in urban traffic and on paved and unpaved roads, and only then license them. In particular, drivers must learn to monitor dashboard gauges and cease operations when meter readings exceed acceptable ranges. Late deliveries cost less than severely damaged vehicles.

d. Repair Maintenance

Repair maintenance is expensive. It requires costly parts and mechanics who receive higher salaries than drivers. The tools and equipment to make repairs are likewise expensive, and, in fact, frequently not available. It is not a great exaggeration to say that, for many vehicles, preventive maintenance is the last chance; because of scarcity of parts and mechanics, repair maintenance may simply not take place. If it does, available resources may be just sufficient for VIP vehicles.

The capacity to perform extensive repairs may grow with the program. When a new system is being established or extended, repairs can be contracted out, provided that repair services exist. As the program grows, it becomes feasible to employ and train mechanics capable of increasingly complex repairs, and to equip them with a set of basic tools. Appendix IV.E.1. gives an example of a useful vehicle repair tool kit.

e. Spare Parts

The ultimate headache! It is bad enough that spare parts are expensive, bu in fleets from multiple manufacturers, they constitute a procurement nightmare. The most practical short-term strategy is to survey the manufactures and models in the fleet, identify the parts most frequently in demand, and stock them in quantity. Establish a reserve fund -- managed petty-cash-style -- for parts that are less in demand. This is important because it avoids time-consuming requisition and procurement procedures. After all, what purchase order clerk will feel a sense of urgency in processing papers for a clutch plate?

* * *

The long-term strategy, admittedly a difficult one to pursue, must be to limit the fleet to the fewest possible appropriate makes and models of vehicles. This requires a unified approach to both procurement and negotiations with different donors. This strategy can be implemented in phases. Make necessary replacements only with the new standard models. Retain non-standard models until their maintenance costs render them uneconomical. Then, if possible, auction them off while they are still running and use the proceeds for parts and tools for the new fleet. This strategy is, in fact, the only one that will achieve sustained improvement. It promises high productivity per vehicle, and lower operating costs in terms of simplified parts and tools acquisition, repair maintenance, and training.

3. ESTABLISHING DELIVERY PATTERNS

Three closely interrelated activities are the key to efficiently managing the storage and delivery system and positively affecting the quality of care at clinical facilities. Delivery interval is the time that lapses between one scheduled delivery to a facility and the next. It is also an expression of the estimated rate of consumption, since supplies are intended to last for the entire interval.

Schedule refers to the predetermined dates (often approximate) on which one facility delivers supplies to another. The system's capacity to deliver the full complement of supplies to all facilities at the appointed time is a measure of its effectiveness.

Routing fixes the order in which facilities receive their deliveries. The choice of route directly affects the efficiency with which supplies are delivered. This includes the cost of fuel and the amount of time required for each delivery.

a. Delivery Intervals and Stock Levels

Weekly deliveries through each level of the storage hierarchy on down to clinical facilities would result in a remarkable savings in inventory holding costs. This approach is scarcely possible, however, because procurements cannot be made with this frequency and the processing costs would be excessive. At the other extreme, it is equally impractical to stock one year's supplies at storage and distribution facilities because there will not be enough space to hold them. Furthermore, unacceptable holding costs will result from excessive stock levels, shelf damage, expiration, and theft. Delivery intervals must be realistically set between these extremes.

Depending on local circumstances and such factors as level of the system, financial, transport, and personnel resources, and time and distance, intervals ranging from one to four months may be appropriate. For example, a central warehouse may resupply regional warehouses quarterly, while regional warehouses supply clinical facilities monthly. Establishing appropriate delivery intervals and stock levels in geographically dispersed facilities requires a systematic and reliable approach.

Under the periodic inventory control system, requisition and delivery dates are predetermined, and maximum stock levels fixed. This permits simultaneous shipment of all commodities, simplifies supply handling, and promotes regular deliveries. Clinical workers have little trouble preparing requisitions because they order only the quantity of each supply that they have consumed. This system is useful at intermediate and peripheral levels in that it minimizes the need for independent decision-making.

The principal drawback is the possibility that unanticipated demand will deplete both regular stocks and safety stocks. This danger can be minimized through systematic studies of the supply system: by establishing delivery intervals in consideration of personnel and transport resources, turnaround time for processing requisitions, and an estimate of the travel time required

for delivery; by establishing stock levels that realistically anticipate demand for the entire delivery interval; and by establishing adequate safety stocks (probably on the high side) for each clinical facility.

Inventory control systems at the central level need greater flexibility than is required at lower levels -- to estimate future demands for the entire system, to be able to absorb fluctuations in supply and demand, and to permit the scheduled flow of supplies down through the system. One of the most practical systems is "Optional Replacement". Stock levels are reviewed at regular intervals and any item that is depleted to a fixed reorder point is automatically reordered up to a predetermined maximum stock level. (The differences, advantages, and disadvantages of various inventory control techniques are discussed in Chapter IV.B.)

b. Scheduling

The objective of scheduling is to organize deliveries so that each facility receives fresh supplies near the end of its delivery interval -- before the last shipment runs out and safety stocks are invaded. Efficient scheduling seeks to minimize costs as well as provide good service. To achieve these goals, the following factors should be considered:

- the average time it takes to (a) process requisitions, (b) assemble supplies, (c) pack supplies, and (d) deliver supplies to a clinical facility
- the number of facilities requiring deliveries
- the average volume of supplies required by each facility
- the total volume of supplies to be delivered
- the number of vehicles available and their individual hauling capacities.

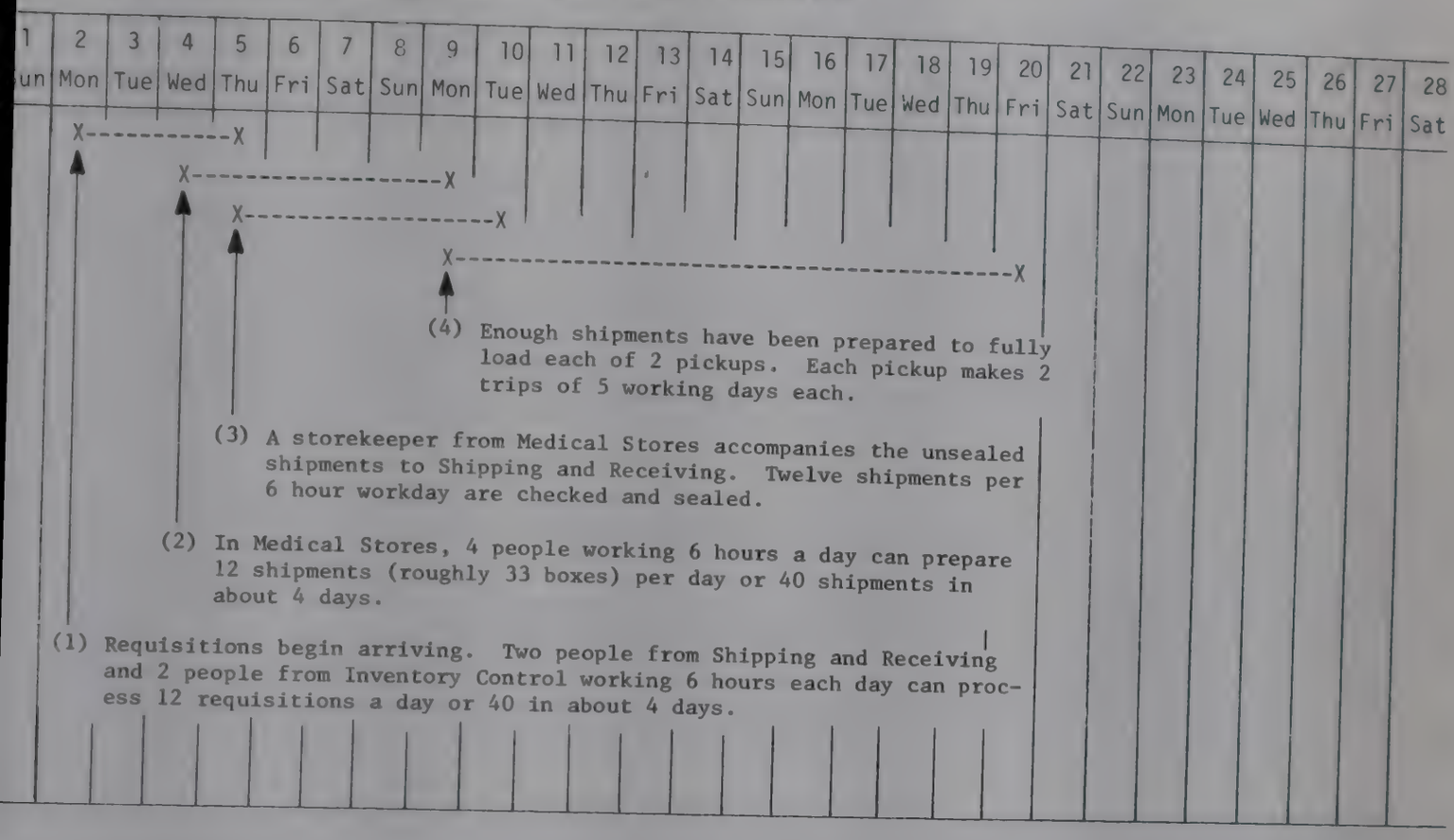
All facilities must receive fresh supplies prior to the end of their delivery interval. If, for example, a warehouse is responsible for 40 clinical facilities and the interval is one month, then the time required to perform all activities necessary for delivery must not exceed a month. If an analysis of relevant factors reveals that six weeks will be required, the objective will not be achieved. Figure IV.E.3. illustrates the application of this approach. Country Study IV.E.1. provides another example of transportation planning.

If the first plan does not produce an acceptable schedule, there are adjustments that can be made. Some of the factors listed above are fixed and cannot be altered. All facilities must be served, the volume of supplies cannot be changed, and the time needed for deliveries will remain the same (unless routes are poorly designed).

On the other hand, by assigning additional personnel to processing requisitions and assembling and packing supplies, the time it takes to perform these activities can be reduced. The big timesaver is arranging for more

Figure IV.E.3.

Development of a Monthly Requisition and Delivery Schedule at a Regional Medical Store


1 Sun
2 Mon
3 Tue
4 Wed
5 Thu
6 Fri
7 Sat
8 Sun
9 Mon
10 Tue
11 Wed
12 Thu
13 Fri
14 Sat
15 Sun
16 Mon
17 Tue
18 Wed
19 Thu
20 Fri
21 Sat
22 Sun
23 Mon
24 Tue
25 Wed
26 Thu
27 Fri
28 Sat
(4) Enough shipments have been prepared to fully load each of 2 pickups. Each pickup makes 2 trips of 5 working days each.
(3) A storekeeper from Medical Stores accompanies the unsealed shipments to Shipping and Receiving. Twelve shipments per 6 hour workday are checked and sealed.
(2) In Medical Stores, 4 people working 6 hours a day can prepare 12 shipments (roughly 33 boxes) per day or 40 shipments in about 4 days.
(1) Requisitions begin arriving. Two people from Shipping and Receiving and 2 people from Inventory Control working 6 hours each day can process 12 requisitions a day or 40 in about 4 days.

The above schedule is based on the following hypothetical information and calculations:

- The regional medical store processes requisitions from and makes deliveries to 40 facilities -- 30 dispensaries staffed by medical auxiliaries, 8 health centers staffed by medical auxiliaries and some physicians, and 2 district hospitals. Monthly requirements of expendable supplies average 0.25 cubic meters for dispensaries, 0.50 cubic meters for health centers, and 1 cubic meter for hospitals.

- Most facilities are located along unimproved roads and four wheel drive vehicles are needed. Two four wheel drive pickups are available, each with a hauling capacity of 4 cubic meters. Shipping boxes average 0.127 cubic meters (1-1/2' x 1-1/2' x 2'). Each pickup will therefore hold about 31 boxes.

- The average monthly requirement for all facilities is 106 shipping boxes.

- The average distance between facilities is 60 miles. The average time for making a delivery is 3 hours (2 hours travel at 30 miles per hour and 1 hour to unload supplies and complete the necessary forms).

- Requisitions begin arriving the first of each month. It takes 2 hours to process one requisition through Shipping and Receiving and Inventory Control. This includes preliminary reviews, obtaining necessary clearances, and posting stock record cards.

- Estimated time to prepare a box in the Medical Stores (40 minutes) and check and seal it in Shipping and Receiving (10 minutes) is a total of 50 minutes. Each facility receives an average shipment of 2.7 boxes. Therefore, the average total processing and packing time is 4.3 hours per shipment (2 hours per requisition plus 2.3 hours for assembling the shipment).

- Since a pickup truck can hold up to 31 boxes, it can serve 10 facilities per trip. With an average delivery time of 3 hours, an average of 2 facilities per day can be served -- more on some days, fewer on other days.

- In all, 20 vehicle-days are required, which is 10 per pickup or 2 trips of 5 workdays each per vehicle per month.

- During the first and last weeks of the month, the pickups can be used to collect supplies for the regional medical store from railroads, airports, inland ports, or by highway from the central medical store. Emergency deliveries can also be made more easily during this period.

- During the last two weeks in the month, Shipping and Receiving and Inventory Control staff review stock records and process stock receipts from the central medical store. Storekeepers handle drug receipts and perform warehouse maintenance functions.

Country Study IV.E.1.

Transportation Planning in Central Asia

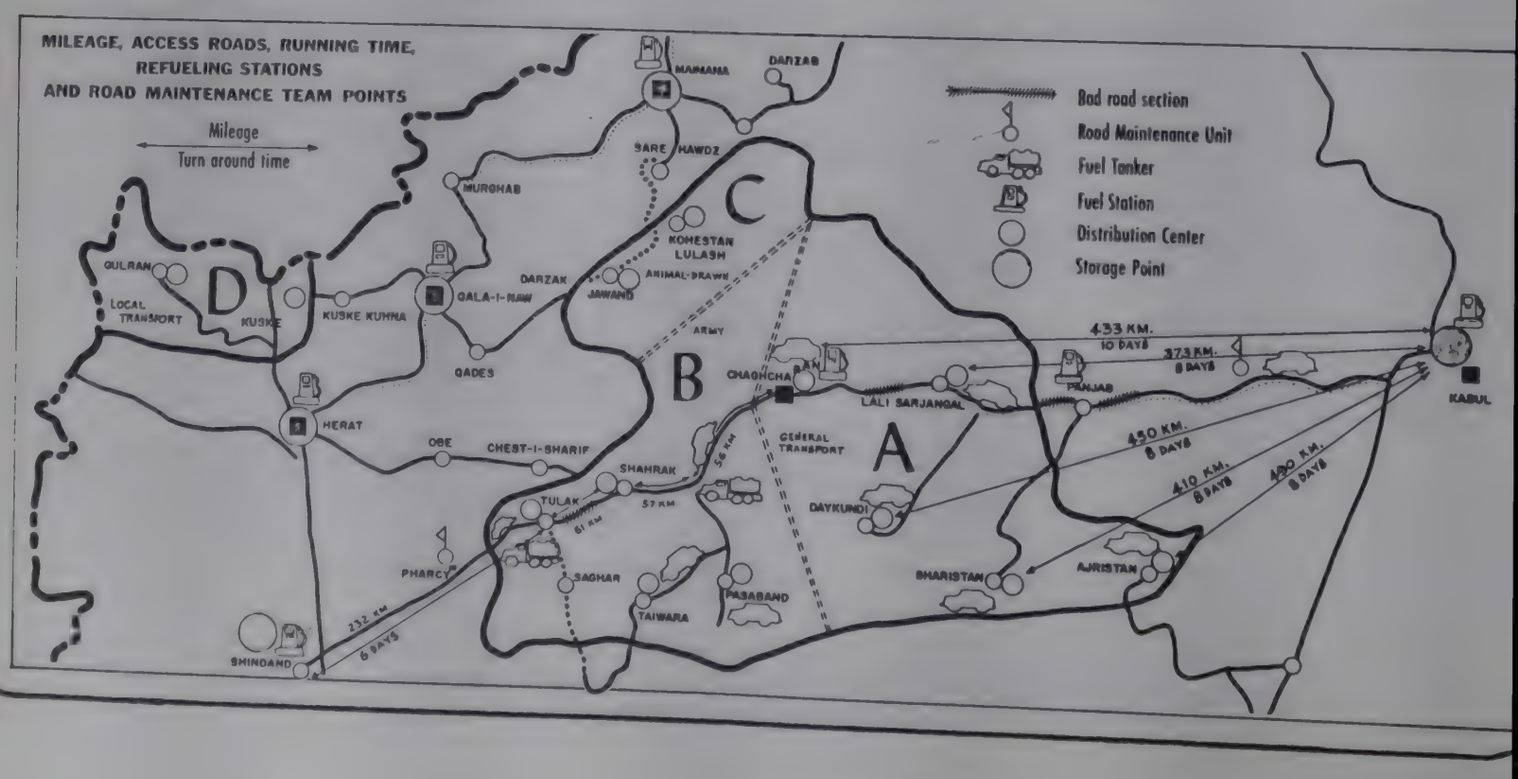
During the years 1970 and 1971, this Asian country experienced an unprecedented drought which was followed by one of the worst winters in its history. Despite the efforts of the Government and international assistance, certain areas were unable to recover from these natural calamities and a major relief effort was mounted. The purpose of the project was to distribute huge amounts of food, clothing, pharmaceuticals, and other supplies to over two million people in an area noted for its mountainous terrain and extreme climate. In this setting, transportation planning and communication were of critical importance.

Planning -- A separate Transportation Division was created, headed by the Transportation Officer, who was responsible for determining transportation requirements, procuring transportation services, planning efficient use of cargo capacities, establishing delivery routes and refueling points, and setting the drop-off points. Efficient use of transportation resources required careful assessment of the geographic area to be served and consideration of available fuel facilities and storage points. The results of this process are shown in the map below. Security, including the institution of roadblocks at some points, and road maintenance were given high priorities. In order to facilitate the movement and control of vehicles, the distressed area was divided into four sectors. Sector A was served by trucks from the capital city, and Sector B, primarily by military trucks with some supplemental commercial carriers. Deliveries to Sector C were by commercial carriers where roads existed and by pack animals as required. Sector D was supplied by local transport.

Road Conditions -- Specific road conditions were carefully considered. The main roads from Kabul in Sector A were generally in poor condition and the steep passes made them impassable during winter months. There was an alternate route to Chaghcharan from Kabul via Bamyan. However, the distance was greater on this route and the condition of the road was also bad. Therefore, the main road from Dykundi was the primary useable road. This route too was difficult and with the beginning of winter its usefulness was restricted. The route from Shindand to Taywara also had a difficult stretch between Shahrak and Taywara. The Pasaband-Taywara route was a third-grade dirt road and the primary route into Sector B. The roads from Herat to Gulran were not primary highways and were considered third-grade. The road from Maimana to Lulash and from Qalaynaw was not completely passable with trucks; thus, 30 kms and 65 kms respectively had to be transited by pack animals. Similar contingency plans were prepared for movement over roads closed by bad weather.

Refueling and Vehicle Maintenance -- Intermediate refueling points were studied and refueling stops were planned in advance. Routes with potential fuel problems were anticipated and appropriate provisions were made to assure adequate fuel. Arrangements were made with the military for assistance in repairs of vehicles disabled near military facilities. Provisions were also made for a mobile workshop to provide on-site repairs.

Procedures at Supply Points -- At the final destinations, i.e., the supply points, procedures were established to encourage efficient vehicle unloading and to assure that no losses had occurred in transit. The driver was required to be present for cargo checking. A vehicle controller at each supply point helped drivers by reviewing their duties, the travel routes, road conditions, and immediate stopping points. (From Operation Help, 1972)



hauling capacity by engaging trucks from other government agencies or commercial haulers. This cuts down on the number of trips required, which are the most time-consuming segment of the delivery routine.

Finally, a principal objective of coordinating delivery intervals, stock levels, schedules, and routes is to minimize the need for "emergency" or interim deliveries. The high cost of operating vehicles has been consistently stressed. Vehicles making interim deliveries go out partially loaded at costs equivalent to regular deliveries. When schedules are tight, they have a displacing effect, moving regular deliveries back. If this occurs frequently enough, stocks are depleted and demands for special attention increase. Creating especially high safety stocks of vital or "life-saving" drugs is one approach to minimizing the problem; it will reduce the number of requests that require immediate response. Responding to requests while on scheduled deliveries to other facilities is another possibility. Finally, facilities with adequate staff might be required to pick up interim requests themselves.

c. Routing

Routing establishes the order and path along which deliveries are made. The principal objective is to achieve the shortest average delivery time and distance per facility. This, in turn, minimizes cost per delivery. Established delivery intervals, characteristics of the transportation network, and the modes of transport available all influence route planning. Different levels of the system have characteristic problems; this section briefly discusses some of them.

The conceptually ideal route is a circular one whereby a truck departs from a storage point and delivers supplies at approximately equal time and distance intervals, returning to the storage point without retracing its path. The goal is to perform deliveries as effectively as possible with the limited salaried time and gasoline available. The least desirable routes are linear or branched ones on which a truck departs from the storage point, makes deliveries along the way, reaches the end of the line, and returns all the way back empty.

Confining the discussion to the regional level for the moment, all that route planning really consists of is working with the existing road network and attempting to establish routes that cover the largest average number of facilities for the distance driven. It is an exercise in choosing the best of suboptimal alternatives. Figure IV.E.4. is a sample Routing Order designed to help assure that drivers follow the established routes. Linear routes that require extensive backtracking are expensive to operate. If there is a high proportion of such routes, local commercial transport, if it is reliable, may be less expensive, since these vehicles can fill the empty backhauls. Another alternative is delivering supplies only as far as the first facility on the route on an appointed day and obliging users to come in and pick up their supplies for themselves. This is feasible when shipments are small, as they are for dispensaries, and when buses, bicycles, or other means of local transport are available.

This chapter has advocated a composite approach to arranging transport. A discussion of routing is a convenient place to reintroduce the subject. A

Figure IV. E. 4.

Sample Routing Order

ROUTING ORDER

MINISTRY OF HEALTH

Department of Medical Supply

Driver _____

Vehicle/Model/Number _____

Warehouse _____

Departure Date _____

Estimated Return _____

Estimated Total Mileage _____

Deliveries will be made in the following order unless road or weather conditions necessitate changes.

1. _____ 6. _____

2. _____ 7. _____

3. _____ 8. _____

4. _____ 9. _____

5. _____ 10. _____

PROGRESS REPORT

Date	Depart	Time	Mileage	Arrive	Time	Mileage

Special Instructions

_____

Dispatcher

regional director, with two pickup trucks and enough money to rent another at delivery time, has little else but careful route planning to satisfy both the schedule and the budget.

At the central level the view is different. The basic principles of route planning and their relative costs still apply, but there are more alternatives to solve the dilemmas they pose. For example, ministry vehicles can be used on the more economical routes. Long one-way trips may be assigned to commercial haulers, saving the ministry the expense of the empty trip back. In a similar manner, a pharmaceutical supplier who makes regular deliveries to regional distributors could drop a shipment off at a warehouse as part of the contract. Fuel savings alone would probably justify these alternatives.

Figure IV.E.5. pictures a hypothetical distribution network. The following comments illustrate in a simplified way the reasoning which might be involved in planning transportation services for this network:

- The road network around large cities is usually well developed, facilitating efficient route planning. This makes it convenient for Ministry vehicles to serve regional Medical Stores 1 and 2 and urban or peri-urban clinical facilities (represented by the large circles).

- Direct deliveries to Regions 3 and 4 would require long trips out and expensive, empty backhauls. It would be cheaper to supply them by rail. Number 3 is obliged to make a short trip to the railway to pick up supplies, but this is less costly than a direct delivery.

- Regional Medical Store 5 is not conveniently served by Ministry vehicles or rail. Therefore, a commercial trucking company that makes scheduled runs between the capital and a city in the south is used. Again, the Ministry pays expenses only one way.

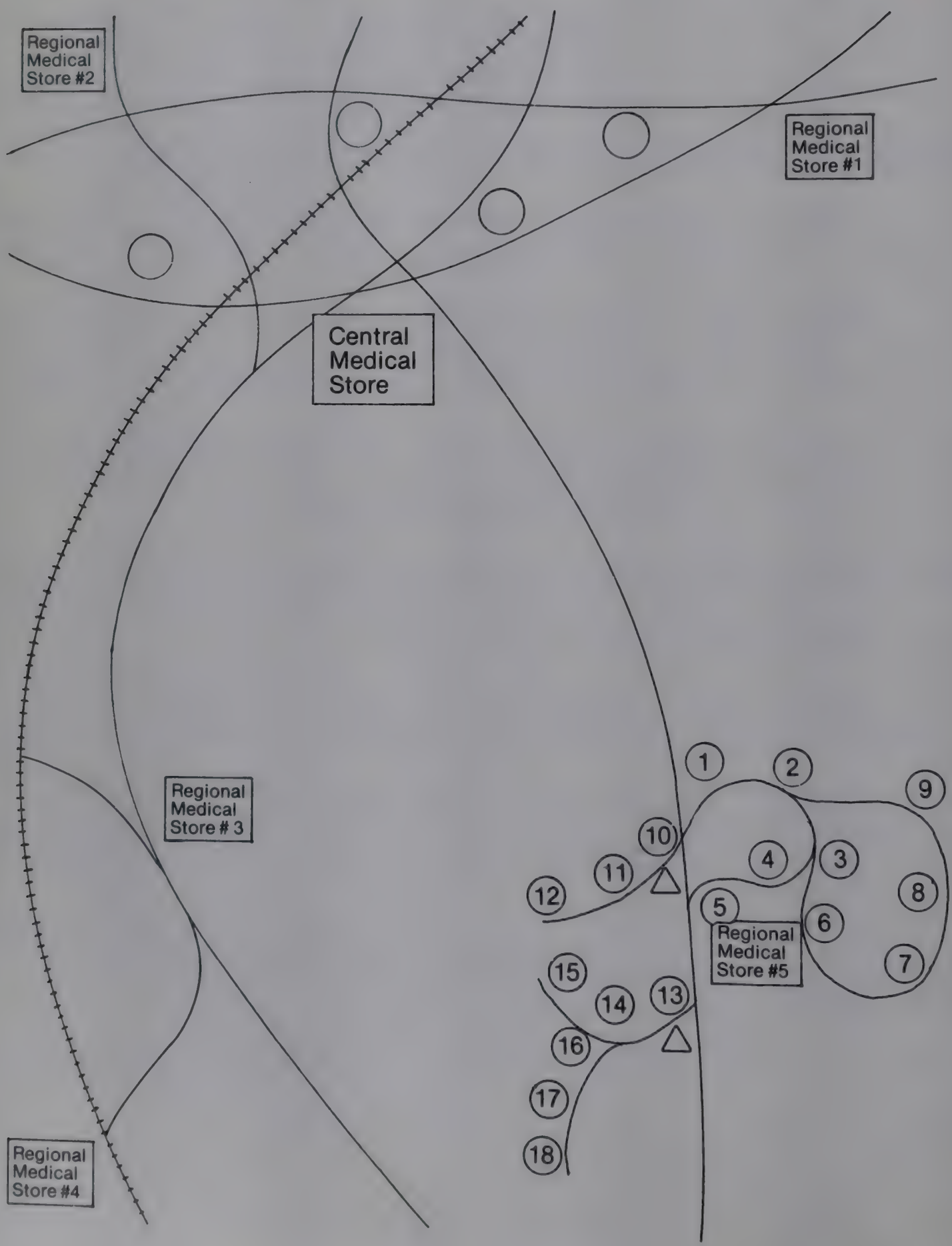
- Regional Medical Store 5 is surrounded by an illustrative network of rural roads and clinical facilities. Facilities 1 through 9 are on a circular route, making delivery by regional store vehicles quite efficient.

- Facilities 10 through 18 lie along linear or branched routes, making it preferable to encourage these facilities to come to the regional store for supplies or to arrange transport with local commercial truckers who might like outgoing drug loads to complement their incoming loads of local produce.

This type of analysis may not reveal a single <u>best</u> strategy, but it should reveal at least one <u>good</u> strategy for maximizing the use of available transportation resources.

Figure IV.E.5.

A Hypothetical Distribution Network



SUMMARY

Efficient delivery requires careful planning and execution. The factors to consider include:

- delivery intervals and stock levels
- transport selection
- schedules
- routes

Available transportation alternatives should be considered in terms of the following factors:

(1) transport cost, which includes vehicle acquisition, maintenance, fuel, and driver salaries
(2) transfer costs, when goods are moved from one mode of transport to another
(3) cost of insurance against damage to goods, loss, or pilferage
(4) port-handling charges
(5) packaging costs, which vary with the type of transport used
(6) transport reliability

The major transport options include:

(1) Ministry of Health vehicles
(2) delivery arrangements with suppliers, obliging them, in contract, to deliver to selected warehouses and clinical facilities
(3) roadway alternatives in the pubic and private sector, taking advantage of existing transport services
(4) railways
(5) air transportation
(6) inland waterways

Vehicles are among the public health system's most expensive expendable supplies. Good maintenance is imperative. Basic issues to consider include vehicle selection, in terms of availability of spare parts and repair and maintenance expertise; preventive maintenance, which minimizes the need for later repairs; driver education, an extension of preventive maintenance; repair maintenance by trained mechanics; and spare parts, which should be stocked in appropriate quantities. The most effective long-term strategy is to limit the fleet to the fewest possible appropriate makes and models of vehicles.

Delivery intervals must be set depending on local circumstances and such factors as level of the system, financial, transport, and personnel resources, and time and distance.

Effective scheduling means organizing deliveries so that each facility receives fresh supplies near the end of its delivery interval. This is accomplished by coordinating delivery intervals, stock levels, schedules, and routes, thus minimizing the need for "emergency" or interim deliveries.

Routing establishes the order and path along which deliveries are made, to achieve the shortest average delivery time and distance per facility and, thereby, the most efficient use of available transport services.

CHAPTER IV.E. REFERENCES

Attwood, P.R.: Planning a Distribution System. London: Gower Press Limited, 1971.

Bowersox, D.J.: Logistical Management. New York: Macmillan Publishing Co., Inc., 1974.

Cone, E.C.: Automotive Operation and Maintenance. Mt. Rainier, MD: Volunteers in Technical Assistance, 1975.

Davis, G.M. and Brown, S.W.: Logistics Management. Lexington, MA: D.C. Heath and Company, 1974.

Leiter, E.F.: Procurement, storage, and distribution of spare parts. UNIDO Symposium. Vienna: United Nations Industrial Development Organization, 1971.

Lloyd, J.S.: Improving the Vaccine Cold Chain II: Progress Report. Geneva: World Health Organization, 1977.

Operation Help Coordination Committee: Operation Help. Kabul, Afghanistan: 1972.

Taff, C.A.: Management of Physical Distribution and Transportation. Homewood, IL.: Richard D. Irwin, Inc., 1972.

UNCTAD: A Transportation Strategy for Land-Locked Developing Countries. New York: United Nations Conference on Trade and Development, 1974.

United Nations: Containers, Pallets and Other Unitized Methods for the Intermoda Movement of Freight: Application to Developing Countries. New York: United Nations Department of Economic and Social Affairs, 1970.

United Nations: Supply Management: Towards Better Use of Equipment and Material Resources in Developing Countries. New York: United Nations Department of Economic and Social Affairs, ST/ESA/SER.E/16, 1978.

UNIDO: Maintenance and Repair in Developing Countries. New York: United Nations Industrial Development Organization, 1971.

U.S. Department of Health, Education and Welfare: Planning for Hospital Pharmacies. Washington, D.C.: U.S. Government Printing Office, 1974.

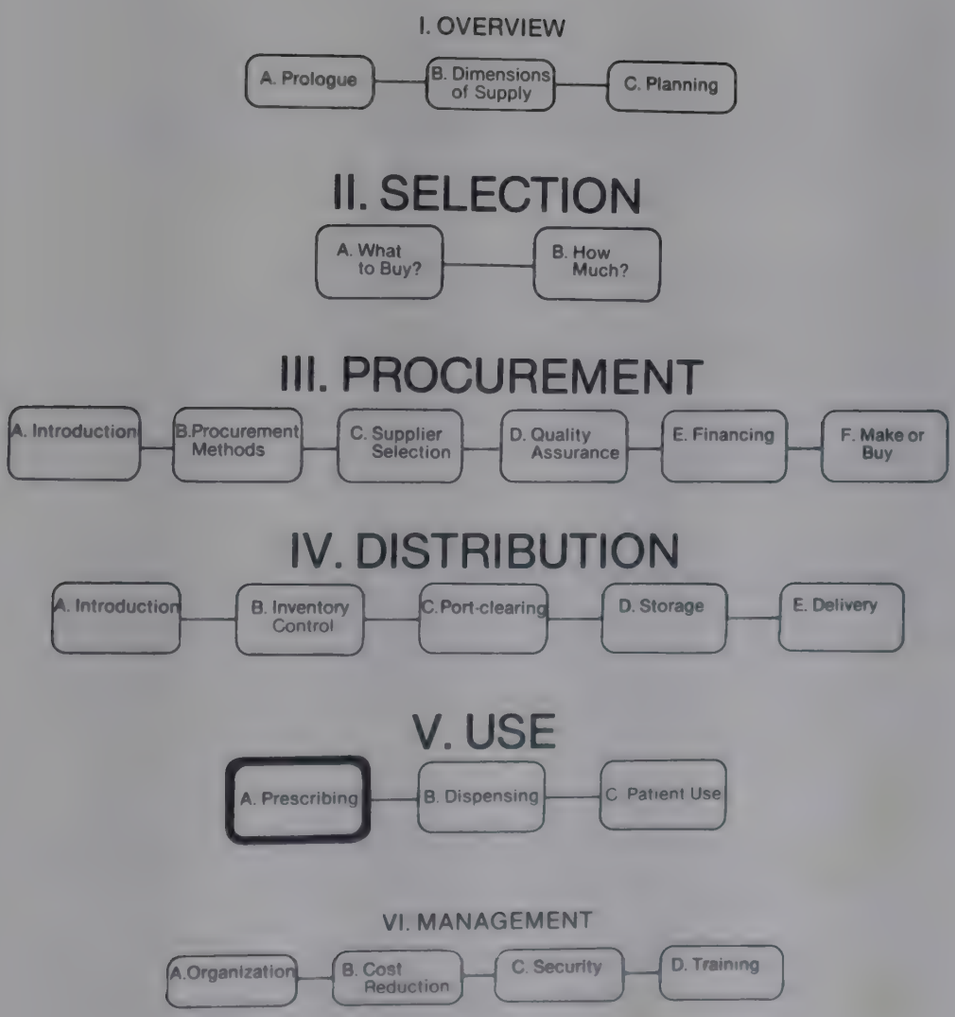
Appendix IV.E.1.

Vehicle Repair Tool Kit

No. of Items	Item	Amount (1980 Prices)
1	Tool box	U.S.$35.00
1	6-inch vise grip	20.00
1	6-inch phillip screwdriver	3.50
1	6-inch standard screwdriver	3.00
1	10-inch crescent wrench	9.00
1	2-inch channellock	6.00
1	Set of Nutdrivers	17.00
1	Set of Allen wrenches	8.00
1	Set combination box wrench	4.00
1	Set metric comb box wrench	4.00
1	Hacksaw and blades	8.00
1	Standard flashlight	5.00
1	Pocket knife	2.50
1	12-foot tape measure	12.50
1	Stiff wire brush	2.00
1	Inspection mirror	2.50
1	6-inch awl	3.00
1	8 oz. ball pein hammer	5.00
1	Voltage-continuity tester	30.00
1	Ignition analyzer	50.00
1	Ignition timing light	50.00
		Total: U.S.$280.00

Chapter V.A.

Promoting Rational Drug Prescribing



	Page
1. THE OCCURRENCE OF IRRATIONAL PRESCRIBING	401
2. TECHNIQUES FOR PROMOTING RATIONAL PRESCRIBING	406
a. Training and Supervision of Medical Practitioners	406
Physicians Medical Auxiliaries	
b. Drug Information	409
Drug Company Promotion Locally Written Reference Manuals and Standard Treatment Norms Drug News Periodicals	
c. Hospital and Regional Drug Committees	418
d. Prescribing and Dispensing Restrictions	419
Prescribing Privileges by Level-of-Use Dispensing Limits Non-Formulary Prescribing	
e. Increasing Cost Consciousness	420
3. DEVELOPING A STRATEGY TO PROMOTE RATIONAL DRUG USE	424
SUMMARY	424
REFERENCES	425

Promoting Rational Drug Prescribing

Rational drug prescribing requires that the medical practitioner make an accurate diagnosis of a condition, select the best drug from those available, and prescribe the drug in an adequate dose for a sufficient length of time, according to standard norms for treatment which were discussed in Chapter II.B. Choosing the best drug requires a judicious weighing of drug effectiveness, safety, and cost.

Choice of therapy, however, is not always a simple matter. There are often several alternative drugs available as well as the option of prescribing a non-drug treatment or no treatment. Even an aid post formulary limited to 15 or 20 items can present more than one therapeutic alternative for many diagnoses.

Ideally, the medical practitioner would like only effectiveness and safety to enter into the selection process. But cost is an unavoidable factor. Even in developed countries, where the per person expenditure for drugs is as much as 40 times that in developing countries and the ability to pay many times greater, governments are working to make medical practitioners aware of the high cost of medicines. In developing countries the situation is even more acute: many modern drugs are so expensive and funds for drugs so limited that, for example, one week of intramuscular antibiotic therapy may consume the annual drug budget for 50 people, and one year of multivitamin drops for one infant may consume seven times that infant's portion of the drug budget.

While the use of expensive medications may be well justified for life-threatening illnesses, these are less common instances. Most illnesses respond to simple, inexpensive drugs and, in fact, often improve with no therapy at all. Use of an expensive drug where a less expensive drug would suffice deprives other patients of needed drugs. and this loss must be heavily weighed in evaluating the need for the more expensive drug.

Assessment Guide V.A. presents questions to stimulate the reader to examine current prescribing practices. In the following pages, we will first consider irrational drug prescribing and its causes, then survey techniques used to promote rational prescribing in developing countries, and, finally, discuss the development of a strategy to promote rational drug prescribing.

1. THE OCCURRENCE OF IRRATIONAL PRESCRIBING

Less than optimal prescribing practices remain a problem in public health programs around the world, often in spite of good intentions and conscientiousness on the part of practitioners. The types of irrational prescribing can be categorized as extravagant prescribing, overprescribing, incorrect prescribing, multiple prescribing (polypharmacy), and underprescribing, which are summarized in Figure V.A.1. Each will be discussed here in turn.

ASSESSMENT GUIDE V.A.

Prescribing Practices of Medical Practitioners

- What are the prescribing habits of health workers like? Are expensive or brand name drugs used when less expensive drugs would provide comparable efficacy and safety? Are drugs dispensed for conditions on which they have no therapeutic effect (such as antibiotics for the common cold)? Are two or more drugs used when one drug would do the job? Are drugs generally used for the correct indications? In the correct dosages?

- What training do physicians, community health workers, and other medical practitioners receive in pharmacology and therapeutics? Is this training adequate in terms of its content and length? Is this training reinforced in practice?

- Are there local treatments of choice or standard norms for treatment? If not, would such norms help improve drug use? If treatment norms exist, how were such norms established? What sources of information and advice were used to determine the norms? Are the treatment norms followed?

- What materials are available to practitioners for reference on therapeutic indications, dosages, or side effects? Are these materials published by drug companies? By scientific bodies? Are there any locally written therapeutics manuals?

- How do medical practitioners learn about new drugs? Through drug company representatives? Through local drug news periodicals? Through specialists, colleagues, or superiors?

- Are physicians, community health workers, and other medical practitioners aware of drug costs? Is cost a consideration in prescribing decisions? Is drug cost mentioned in medical and auxiliary training?

- Are prescribing privileges limited by the prescriber's level of training or by the type of health facility dispensing the drugs? If not, would such limitations improve drug use? If so, are these limitations reasonable? Do they allow practitioners to function within their levels of expertise, without exceeding the limits of their training or ability?

- Are there local hospital, district, or regional drug committees which review drug selections and drug use patterns at various health facilities? If so, what are the responsibilities and duties of these committees? How active are they in promoting judicious, economical drug use? Who serves on the committees?

- Are there limits on the amount of medication that can be dispensed at any one time? Are these limits reasonable, or do they result in suboptimal treatment of potentially serious diseases?

Figure V.A.1.

Types of Irrational Drug Use*

Type of Irrational Drug Use	Occurs if a drug is prescribed when:
Extravagant Prescribing	• a less expensive drug would provide comparable efficacy and safety • symptomatic treatment of mild conditions diverts funds from treating serious illness • a brand name is used where less expensive equivalents are available
Over-prescribing	• the drug is not needed • the dose is too large • the treatment period is too long • the quantity dispensed is too great for the current course of treatment
Incorrect Prescribing	• the drug is given for an incorrect diagnosis • the wrong drug is selected for the indication • the prescription is prepared improperly • adjustments are not made for co-existing medical, genetic, environmental, or other factors
Multiple Prescribing	• two or more medications are used when one or two would achieve virtually the same effect • several related conditions are treated when treatment of the primary condition will improve or cure the other conditions
Under-prescribing	• needed medications are not prescribed • dosage is inadequate • length of treatment is too brief

* Adapted from Working Party, Council of Europe, 1976.

Extravagant prescribing is the use of an expensive, usually newer, drug when an inexpensive older drug would provide the same effectiveness and safety. In one African country, for example, it has been estimated that 5 to 18 percent of the drugs prescribed in district and regional hospitals and as many as 40 percent of the drugs prescribed at the main teaching hospital represent selections of "extravagant" drugs.

Overprescribing might at first seem impossible in health programs which face constant drug shortages, but the frequent use of drugs for conditions for which they are ineffective is one cause of shortages. In one study of prescribing habits in the United States, physicians reported that for more than 40% of the prescriptions issued to patients with trivial conditions, they did not expect significant therapeutic benefit. A British study found the use of vitamin B_{12} to exceed the justifiable medical need by at least four times.

Sulfa drugs, antibiotic syrups, and other antibiotic preparations remain popular treatments for infantile diarrhea in some countries, despite the evidence that antibiotics are of no benefit in the majority of such cases. Antibiotics in general have acquired a reputation as being "cure-alls". Even among government-trained rural public health workers, one finds the use of intramuscular pencillin or oral ampicillin for the treatment of headache, backache, and a variety of other non-bacterial conditions for which they are, in fact, ineffective. Aside from the economic waste which these practices entail, antibiotic resistance is growing steadily, and it has been postulated that this may lead to epidemics similar to those of pre-antibiotic days.

Incorrect prescribing results in a patient getting the wrong medication for his condition. It can occur either because of an incorrect diagnosis or because of an inappropriate drug selection for a recognized condition. For example, limited diagnostic facilities may force a practitioner to treat "presumptively" the condition most likely to occur; this may be the best approach, even though it can result in some errors. Often more dangerous are the other cases of incorrect prescribing: the continued use of tetracycline pediatric syrups in some African and southeast Asian countries despite well documented evidence of their side effects and the existence of good alternatives; the persistence in the use of aminophenazones (aminopyrine and dipyrone) in Africa and South America despite potentially fatal toxic reactions and readily available alternative analgesics; and the use of growth-stunting and tumor-producing anabolic male hormones for the treatment of weight loss and appetite loss in children.

Multiple prescribing is the unnecessary use of more than one medication for the same condition. Some patients on multi-drug therapy have obtained drugs from several sources, but multiple prescribing usually occurs because the health worker prescribes more drugs than necessary. In some countries in the eastern Mediterranean region, the average number of items per prescription is over four, in contrast to an average of less than 1-1/2 in other countries. A 1974 survey of drug consumption in Afghanistan showed that 41 percent of the dollar value for the top ten groups of drugs was for combination drugs. Fourteen percent of the total was for a single highly irrational combination of penicillin, streptomycin, quinine, vitamins A and D, expectorants, and anti-histamine. An additional 10 percent was for an analgesic combination for which simple aspirin would have sufficed in most cases. In addition to the cost of unnecessary multiple prescribing, the risk of significant adverse

interactions -- which occur for about one in twelve prescriptions -- must be considered.

Underprescribing might seem inevitable under conditions of shortage, but there are therapeutic and non-therapeutic ways of using drugs when there are limited amounts. In some areas the response to shortage is to reserve drugs for only the sickest, while in other areas health workers use lower doses to treat more people. If the reduced dose is below therapeutic levels, as it often is, it means that no one is cured. Moreover, sub-therapeutic antibiotic treatment presents the ideal circumstance for the development of resistance. Occasionally government policies intended to conserve medications limit prescriptions to sub-optimal doses. Self-prescribed use of antibiotics may also contribute to bacterial resistance because the high cost of black market drugs as well as poor understanding of antibiotic use leads to undertreatment. For optimal use of limited drug supplies, treatment should be reserved for patients most likely to benefit from it and administered in adequate dosages.

The reasons for irrational drug prescribing are multiple and complex. In brief, the main causes identified by those who have studied prescribing behavior are the following:

(1) Inadequate training in clinical pharmacology -- Despite the daily use of medicines in clinical practice, formal training in drug use is usually brief and often limited to the early part of medical training.

(2) Lack of continuing education and supervision -- For the medical auxiliary as well as the practicing physician, there is usually little opportunity for regular review of their prescribing habits. In addition, there are few opportunities for them to learn about new drugs from unbiased sources.

(3) The practitioner's inappropriate desire for prestige -- In some areas a "good doctor" is expected to use many different drugs and prescription of multiple drugs is falsely considered a sign of good care.

(4) Promotional activities of drug company representatives -- The role of commercial interests in promoting irrational and costly prescribing has been well documented and cannot be over-emphasized. Even where the choice of drugs is limited by centralized purchasing, company representatives frequently promote overuse of drugs.

(5) Lack of time due to heavy patient load -- Medications are often given out to help end a patient visit, or prescribed "just in case", to avoid a return visit.

(6) Pressure from patients -- Even in the most remote areas, patients quickly come to expect that every symptom has a medicine to cure it. Because patient education can be slow, time-consuming, and tiring, practitioners often give in to the request for medicines.

(7) Fear-induced prescription -- Diagnoses are rarely made with absolute certainty and the course of an illness cannot be predicted exactly. Medical practitioners often try to "protect" themselves against this uncertainty by extravagant, multiple, or overprescribing.

(8) Incorrect generalization about a drug from limited experience -- Unexpectedly favorable results or unfavorable side effects are sometimes seen with the use of a drug. Although these results may be totally unrelated to the drug, practitioners may over-react and, depending on the result, later overprescribe or underprescribe on the basis of this anecdotal information, rather than on the basis of scientific evidence.

Although the manifestations of irrational drug prescribing are increasingly well documented and the reasons for irrational prescribing are more clearly understood, the means for overcoming prescribing abuses and promoting rational prescribing have not been as systematically studied. In general, efforts to influence prescribing practices through voluntary means or involuntary controls have received better support and have been more successfully implemented where prominent practicing physicians within the medical system are actively involved in the process.

Attempts to influence prescribing focus on the training process, on drug information sources, on the planning process, or on formal prescription controls. Efforts have been made at the national, regional, local, and individual institution levels. Most of the strategies for promoting rational drug prescribing are not mutually exclusive. In fact, a comprehensive policy should aim at influencing prescribing behavior at all levels of the system.

2. TECHNIQUES FOR PROMOTING RATIONAL PRESCRIBING

a. Training and Supervision of Medical Practitioners

Physicians

Physicians control the use of scarce drug resources not only through their own prescribing practices, but also through their influence as instructors, supervisors, and trend-setters for the often larger force of medical auxiliaries. (And to a certain extent, physicians are also trend-setters for black market drug use.) Thus, a sound training in rational drug prescribing can have a significant effect.

Clinical pharmacology is frequently a neglected subject in the medical curriculum and often relegated to a brief period early in training. A group of European medical educators concerned about their own teaching of clinical pharmacology has recommended that training include:

(1) Basic pharmacology -- Principal mechanisms of drug action, metabolism, absorption, distribution, and elimination.

(2) Clinical pharmacology -- Study of the different classes of drugs with regard to clinical efficacy, risks, pharmacokinetics, drug-drug interactions, drug-disease interactions, drug-genetics interactions, and the concept of clinical trials.

(3) Therapeutics -- Joint meetings with clinicians and practitioners

Country Study V.A.1.

Clinical Pharmacology in Sri Lanka

The Department of Pharmacology at the Faculty of Medicine in Colombo is staffed by faculty members who have received overseas training in pharmacology and therapeutics. Pharmacology is taught as a clinical course during the third and fourth years of the five year medical course, rather than as a pre-clinical course in the first or second year. Students are taught through lectures as well as integrated clinical teaching sessions in which physicians, clinical pharmacologists and, in some cases, microbiologists meet with students at the bedside to discuss drug therapy in the context of the whole clinical picture.

Students learn to consider the difficulties which patients may have in obtaining or using drugs, to weigh cost factors in their selection of drugs, and to carefully consider the benefits and potential risks of each medication. Students learn drugs by their medical (generic) names.

During the third year students are given an introduction to pharmacological principles, adverse drug reactions, drug interactions, and the concept of controlled clinical trials. A pharmacology lecture series covers the drugs within each pharmacological category. Special topics such as metabolic disturbances and drug adjustments for various disease states are also considered.

During the fourth year the emphasis is more strictly on therapeutics, and teaching sessions focus on specific disease rather than specific drugs. Fever, diarrheal disease, parasitic disease, pain, hepatitis, cirrhosis, anemia, bronchial asthma, respiratory infections, diabetes mellitus, cardiovascular disease, and kidney disease are among the conditions covered.

In addition to teaching medical students, the clinical pharmacology faculty actively promotes rational drug prescribing through several other channels, including:

- Participation on the National Formulary Committee,
- Participation in seminars and meetings of Sri Lankan medical societies for continuing education, and
- Authorship of articles in the local medical journals, including The Prescriber and The Sri Lanka Practitioner.

centered on the individual patient and his personal circumstances and stressing economical prescribing.

Other important considerations for the student who will be practicing in a public health program include the use of medical (generic) names, consideration of cost as a factor in weighing the safety and efficacy of a drug, and attention to supply logistics and the effects of transportation, storage, and drug quality on the availability and stability of drugs.

The value of medical faculty trained in clinical pharmacology is exemplified in Country Study V.A.1., which describes the progressive role that it has played in one Asian country. Clinical pharmacology fellowships are also available through international organizations such as WHO.

In addition to giving increased attention to clinical pharmacology, medical faculties should increase medical student awareness of the importance of pursuing drug information throughout their clinical training and practice. Figure V.A.2. illustrates the framework which one prominent clinical pharmacologist has proposed to help medical students accomplish this task.

In some areas local associations of physicians or auxiliary medical workers have identified their own need for continued training in therapeutics and have participated in seminars and other medical meetings for keeping up

Figure V.A.2.

Towards Parity for Therapeutics in Clinical Teaching

Two quite different methods of teaching are used in clinical medicine. In one, packages of knowledge, such as books and lectures about diseases and their management, are presented to the students for assimilation. In the other, the student learns how to take a history and examine people and then practises these skills under supervision on actual patients in the care of his teachers. Both methods are needed, and are used in all British medical schools to teach diagnosis; but only the first is widely used to teach clinical pharmacology and therapeutics, because there are too few clinical pharmacologists for "clinical apprenticeship" teaching to be practicable. At present, therefore, students learn very little about treatment from the cases that they see, and that is a great waste of potentially valuable experience. But students could learn from this experience if they knew how to organise it in their minds—that is, if they knew what questions to ask themselves. The accompanying list of questions tries to help them do this. It is arranged in fairly logical sequence to make it easy to use and to remember, like the conventional headings for history-taking and clinical examination.

The use of such a question list has several important advantages: (a) it makes clear to the student that it is his responsibility to learn about drugs, and not someone else's to teach him; (b) it helps him to develop habits of considering and discussing drug therapy critically; (c) it makes it easy for clinical teachers without special training in clinical pharmacology to teach on topics related to the treatment of their patients (this might in time correct the bias towards discussion of diagnosis which has been prominent at least since the day when Osler said, "there are three important principles in treatment: diagnosis, diagnosis and diagnosis"); (d) the questions tend to facilitate discussion of treatment by everyone concerned (in the ward this includes the patient himself, the nurses, the ward pharmacist, and even perhaps on occasion the patient's visitors). The question list is distributed not only to all clinical students and teachers but also to all other members of the medical staff, to ward and outpatient sisters, to the pharmacy staff, and to the medical-school library, so that everyone who may be able to help a student can understand what he is trying to do.

Source: A. Herxheimer: *The Lancet II* (7996): 1186-1187, (November 27) 1976.

To all clinical students

QUESTIONS TO ASK YOURSELF ABOUT DRUGS

One of your main chances to learn about drugs occurs while you are doing clinical work. The questions below will help you to learn more systematically from this experience. Ask yourself these questions to assess your knowledge. If you cannot answer them for yourself discuss them with those who are treating the patient.

Look at the treatment sheet at the end of the patient's bed or the outpatient prescription form. Some of the drug names may be unfamiliar. You will need to find out about these.

1. *Name*	For each drug listed, what is the approved or generic name?
2. *Class*	To what class does each drug belong e.g., diuretic, phenothiazine ?
3. *Aim*	What aim is to be achieved with each drug? What disorder of function is to be corrected, or what symptom relieved?
4. *Observations*	What observations can be made to judge whether the aim has been achieved? When should they be made and by whom?
5. *Route and dosage*	By what route, in what dose, and at what intervals is each drug to be given, and why? In what forms does each drug come?
6. *Alternatives*	What other remedies might have been chosen instead of these drugs? Is this drug a good choice efficacy, safety, cost ?
7. *Duration*	How long should treatment go on, and when and how could a decision be made to stop?
8. *Elimination*	How is the drug eliminated? Will the patient's illness change the usual pattern of distribution and effects of the drug?
9. *Unwanted effects*	What undesirable effects may occur from this drug? Are they acceptable? What is their approximate frequency?
10. *Interactions*	Are there any other drugs which should be avoided while the patient is receiving this treatment? If yes, which are they and why should they be avoided?
11. *Patient's Ideas*	What does the patient believe about the drug? What has he been told about it? And what has he remembered? Does he need additional information?

with current drug information. Government health programs sometimes sponsor presentations for health personnel. These sessions can foster cooperation when, later, a new program for drug procurement and distribution is introduced.

Medical Auxiliaries

Medical auxiliaries are commonly the first point of contact for patients in all but the urban areas. Improper use of medicines by these health workers can be dangerous as well as wasteful. On the other hand, prompt and appropriate use of medicines can save lives and prevent the progression of disease to a more debilitating and more expensively treated state.

Many countries find it useful to limit medical auxiliaries to a specific drug list and to provide a pocket drug reference manual based on this list. Medical workers are encouraged to use the manuals rather than to depend on recall for selecting drugs and drug dosages for all but the most frequently treated conditions. Figure V.A.3. illustrates the content and format of a pocket-sized drug reference manual used in the Western Pacific.

Formal training in pharmacology and therapeutics provides a sound basis for medical auxiliaries to prescribe standard drugs and to understand the uses of new drugs which are introduced into their drug lists. An example of the curriculum used for such a training program in Tanzania appears as Country Study V.A.2.

Like their physician counterparts, medical auxiliaries tend to become more casual and occasionally rather creative in their prescribing habits once they have been practicing for several years. Regular supervision by senior medical auxiliaries or medical officers, with attention to the medical auxiliaries' prescribing habits, is essential to the continued rational use of drugs. Section 4 in Chapter VI.A. discusses supervision in greater detail.

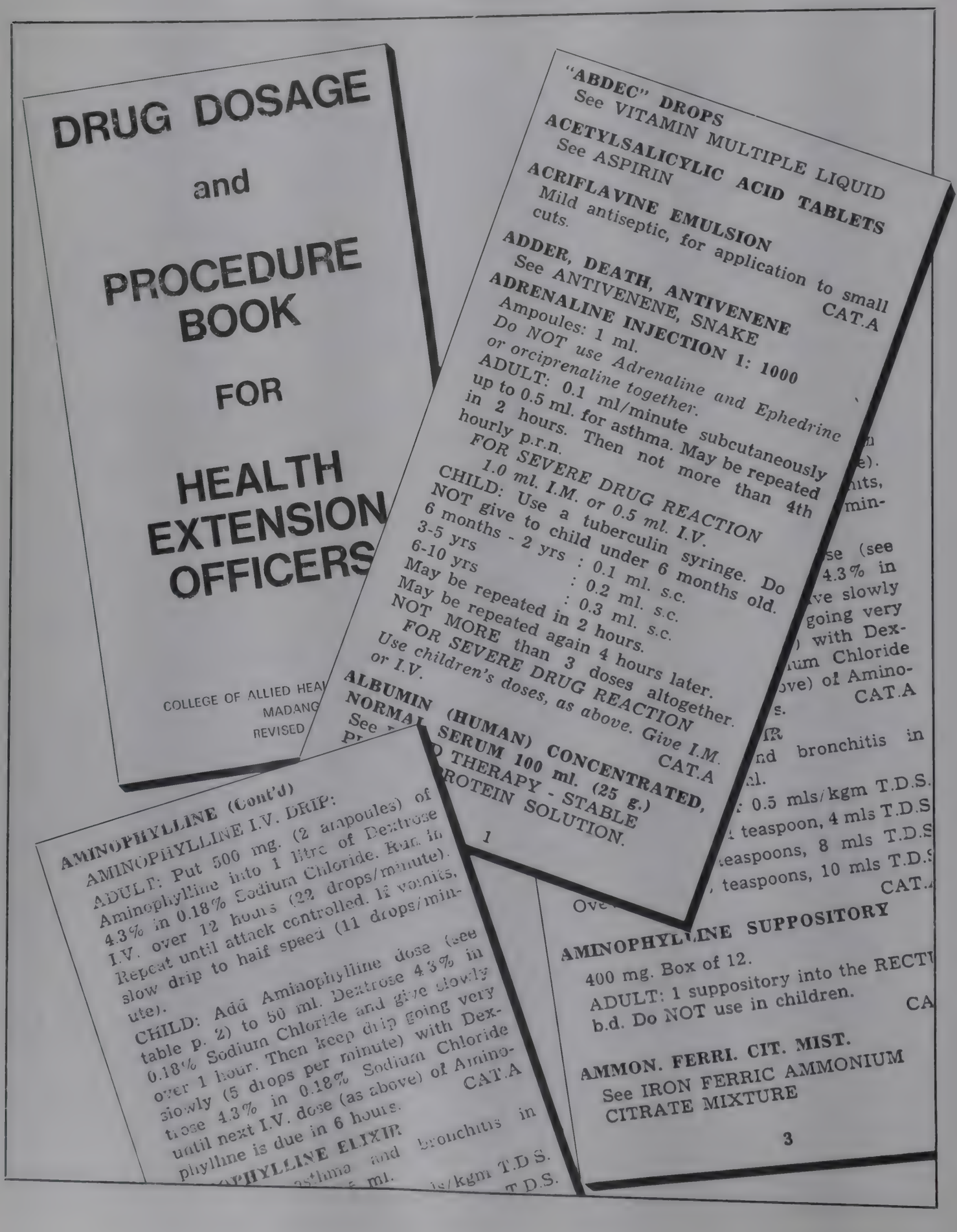
Personal supervision and case-review are, however, often difficult or impossible. So, in many programs, village health workers and other medical auxiliaries are required to keep a brief listing of patients seen and diagnoses made. If the prescribed treatment is also recorded on this form, then the practitioner's prescribing habits can be quickly reviewed and suggestions for improved drug therapy can easily be made. In-service refresher courses and sharing of cases by medical auxiliaries can be organized locally, using the health center as a base and the doctor as educator.

b. Drug Information

Once out of formal training, a medical practitioner develops his own prescribing practices, which are then influenced only by whatever new drug information he receives. Studies from the United States and Great Britain show that most physicians first learn of a new product from drug company representatives and advertisements, but that the decision to actually use a drug is based frequently on advice from consultants and on medical journal articles. But, in isolated communities, drug company promotion is often the strongest influence. Promotional effort is proportionately greater in developing countries, where access to consultants is limited by distance, poor communication, and a smaller number of available consultants, and access to medical journals is limited by language, expense, and the availability of time.

Figure V.A.3.

Excerpts from a Drug Manual for Medical Auxiliaries



DRUG DOSAGE

and

PROCEDURE BOOK

FOR

HEALTH EXTENSION OFFICERS

COLLEGE OF ALLIED HEA
MADANG
REVISED

"ABDEC" DROPS
See VITAMIN MULTIPLE LIQUID

ACETYLSALICYLIC ACID TABLETS
See ASPIRIN

ACRIFLAVINE EMULSION CAT.A
Mild antiseptic, for application to small cuts.

ADDER, DEATH, ANTIVENENE
See ANTIVENENE, SNAKE

ADRENALINE INJECTION 1: 1000
Ampoules: 1 ml.
Do NOT use Adrenaline and Ephedrine or orciprenaline together.
ADULT: 0.1 ml/minute subcutaneously up to 0.5 ml. for asthma. May be repeated in 2 hours. Then not more than 4th hourly p.r.n.
FOR SEVERE DRUG REACTION
1.0 ml. I.M. or 0.5 ml. I.V.
CHILD: Use a tuberculin syringe. Do NOT give to child under 6 months old.
6 months - 2 yrs : 0.1 ml. s.c.
3-5 yrs : 0.2 ml. s.c.
6-10 yrs : 0.3 ml. s.c.
May be repeated in 2 hours.
May be repeated again 4 hours later.
NOT MORE than 3 doses altogether.
FOR SEVERE DRUG REACTION
Use children's doses, as above. Give I.M. or I.V.
CAT.A

ALBUMIN (HUMAN) CONCENTRATED, NORMAL SERUM 100 ml. (25 g.)
See PLASMA THERAPY - STABLE PROTEIN SOLUTION.

1

AMINOPHYLLINE (Cont'd)
AMINOPHYLLINE I.V. DRIP:
ADULT: Put 500 mg. (2 ampoules) of Aminophylline into 1 litre of Dextrose 4.3% in 0.18% Sodium Chloride. Run in I.V. over 12 hours (22 drops/minute). Repeat until attack controlled. If vomits, slow drip to half speed (11 drops/minute).
CHILD: Add Aminophylline dose (see table p. 2) to 50 ml. Dextrose 4.3% in 0.18% Sodium Chloride and give slowly over 1 hour. Then keep drip going very slowly (5 drops per minute) with Dextrose 4.3% in 0.18% Sodium Chloride until next I.V. dose (as above) of Aminophylline is due in 6 hours. CAT.A

AMINOPHYLLINE ELIXIR
...asthma and bronchitis in ... ml.
...s/kgm T.D.S.
...T.D.S.

...se (see
...4.3% in
...ve slowly
...going very
...) with Dex-
...um Chloride
...ove) of Amino-
...s. CAT.A
...nd bronchitis in
...l.
...: 0.5 mls/kgm T.D.S.
...4 teaspoon, 4 mls T.D.S
...teaspoons, 8 mls T.D.S
..., teaspoons, 10 mls T.D.S
CAT.A

AMINOPHYLLINE SUPPOSITORY
400 mg. Box of 12.
ADULT: 1 suppository into the RECTU
b.d. Do NOT use in children. CA

AMMON. FERRI. CIT. MIST.
See IRON FERRIC AMMONIUM CITRATE MIXTURE

3

Country Study V.A.2.

Therapeutics Training for Rural Medical Aides in Tanzania

After completing a 2-3 year course (depending on previous education) which includes 800-1200 hours of theory and 1600-2400 hours of practical work, RMAs are responsible for: (1) the diagnosis and treatment of common diseases; (2) emergency first aid treatment; (3) promotion of health through community education and environmental activities; (4) supervision of health workers responsible for maternal and child health programs; and (5) management of the rural dispensary. The 100 hour curriculum for pharmacology and management schedules enables the RMA to prescribe and administer correct therapeutic management schedules for the common conditions treated at dispensary level, using only such drugs as are permitted by the scheduled drug list for dispensaries.

PHARMACOLOGY (45 hours total)

A. General Pharmacological Principles (10 hours)

1. Action of Drugs on the Body
   1.1. The RMA must be able to explain the meaning of the following concepts in relation to drug action: (a) therapeutic dose, (b) lethal dose, (c) overdose, (d) toxic effect, (e) allergic effect, and (f) side effect.
   1.2. The RMA must clearly distinguish between: (a) specific therapy, (b) symptomatic therapy, and (c) placebo effect.
   1.3. The RMA must be able to describe: (a) the main routes of administration of drugs, (b) the meaning of "blood level" of a drug, and (c) the main methods of elimination of drugs from the body with examples taken from the dispensary drug schedule.

2. Responsibilities of Medical Workers: The RMA must be able to: (a) write a prescription in the correct form, (b) state the dangers of over- and underprescribing with some examples, (c) explain to patients the importance of regular dosage and continuing the full course of treatment, (d) state the dangers of reducing treatment courses and discontinuing drugs, (e) explain the disadvantages of multiple prescribing, and (f) arrange that drugs are kept from children.

B. Drugs Acting on Living Organisms (20 hours): For antiseptics, antibacterial agents, and antifungal agents the RMA should be able to name the agent used for each condition or organism, describe the correct usage for each agent, and identify the effects and side effects of each agent. Particular attention is paid to the use, misuse, and potential dangers of penicillin and the proper use of tuberculosis medications.

C. Drugs Acting on Body Systems (10 hours): For each of the items on their drug list, the RMA must state: (a) normal indication for use, (b) normal dosage in adults and children, (c) usual action in the body, (d) common toxic effects, if any, and (e) any important contraindications.

D. Therapeutic Action of Health Principles (5 hours): The RMA must be able to explain: (a) the natural resistance and repair activity of the body which heals most diseases even without treatment, (b) effect of rest and elevation of limbs in healing processes, (c) effect of nutrition on resistance to infection, (d) use of exercise and rehabilitation in certain conditions (e.g., leprosy, polio), and (e) use of home rehydration mixtures in diarrheas.

MANAGEMENT SCHEDULES (55 hours total)

A. Common Conditions (30 hours): For each common condition normally treated in a dispensary the RMA must be able to: (1) state the advised regime -- this includes advice on rest, diet, fluids, and duration of treatment; and (2) name the drug used -- for common drugs, give the normal method of administration, duration of treatment, common side effects; for less common drugs, demonstrate ability to refer rapidly to the schedule or therapeutic index.

B. Emergencies (20 hours): First-line management of surgical emergencies.

C. Therapeutic Index (5 hours): The RMA must be able to use the published therapeutic index (management schedule) to: (1) ascertain correct children's doses, (2) identify side-effects of drugs, and (3) identify indications and correct administration of less commonly used drugs.

MANUALS: Manual of Pharmacology by Dr. I. A. Mtulia; Management Schedules for Rural Health Units by Dr. P. Petit.

TEXTS: Pharmacology for Nurses by Trounce; Clinical Pharmacology by Lawrence.

Adapted from Curriculum for Rural Medical Aide Training, by Wizara Ya Afya, Tanzania, 197[illegible].

The intensity of the promotional effort is reflected in the following ratios of company representatives to physicians in various countries. These figures show that each drug company representative in a developing country is responsible for fewer doctors, and thus has a potentially greater influence on each one.

Country	Ratio of Company Representatives: Doctors
United Kingdom	1:20
United States	1:10
Ecuador	1:8
Colombia	1:5
Tanzania	1:4
Guatemala	1:3
Brazil	1:3

As alternatives or supplements to drug company promotional activities, public drug programs in developing countries have developed several other drug information sources:

- locally prepared reference manuals,
- drug news periodicals,
- drug information centers.

After first considering the role of commercial drug promotion in public programs, each of these drug information sources will be discussed.

Drug Company Promotion

"The incidence of disease cannot be manipulated and so increased sales volume must depend at least in part on the use of drugs unrelated to their real utility or need..." (Statement of former medical director of a large pharmaceutical company to the United States Senate).

The extent of bias and misinformation on the uses, side effects, and contraindications of drugs in drug promotion has been widely noted. Aside from the potential negative health consequences, this promotion also has certain disruptive effects on the smooth operation of public drug supply systems. Government drug programs in South America, Africa, and Asia have found that company representatives visiting government physicians can have the following influences:

- Create demand for brand name drugs, often despite evidence from quality control testing that government-procured or generically-named drugs are of comparable quality;

- Create imbalances in supply by promoting consumption of alternative drugs. For example, the company with the contract for ampicillin will promote its use with the hope of selling more than the original order. Shortages are thus created for some drugs, while excesses occur for others;

Country Study V.A.3.

Controls on Pharmaceutical Company Representatives in Selected Countries

India -- Company representatives may only refer to those indications for which the drug has been approved and may only give information that was contained in the product license application and was subsequently approved by the Drug Controller.

Costa Rica -- All company representatives are required to be pharmacists or physicians, but there is no control over the content of presentations.

Cuba -- No representative of private pharmaceutical companies is allowed to visit physicians.

Czechoslovakia -- Expert informers from the state trust of pharmaceutical manufacturers -- United Pharmaceutical Works -- inform physicians directly about new drugs following a plan which is approved in advance by the Ministry of Health.

Sweden -- To make presentations to hospital house physicians, company representatives must first obtain approval from the hospital drug committee. The committee will allow only essential information on new drugs or drug developments to be presented in a formal meeting. Individual visits from company representatives to physicians are not allowed.

United Kingdom -- Despite a 1967 recommendation that the government "should consider whether... measures should be taken to discourage visits to doctors by representatives," visits by company representatives are still predominant prescribing influences. However, as of 1973, the company representative must present the medical practitioner with an approved data sheet before any promotional material is presented. The data sheet contains an objective statement about the uses, contraindications, and warnings for the product and must be in accordance with the registration license.

United States -- Regulation of the activities of company representatives is accepted as part of the role of the pharmacy and therapeutics committees at many hospitals. The committees often control the hours, location, and method of presentation in which the representatives can contact physicians. Sometimes they are required to register at the pharmacy upon arrival and to visit only those physicians with whom they have a formal appointment -- "stopping by" is not allowed.

- Create demand for new drugs by encouraging physicians to request their purchase; this often occurs where there is no clear evidence to indicate comparatively greater effectiveness or safety.

Despite the difficulties created for public drug programs by company representatives, few developing countries have taken action to control them. It could be argued that, where the selection of drugs and the quantities distributed are rigidly controlled by the public procurement program, drug companies find little value in promoting their products and their activities are minimal. But, in many public drug procurement programs, drug company representatives continue to have a considerable impact. Several courses of action are open, ranging from complete prohibition of promotional activities to regulation designed to decrease their bias and increase the completeness and accuracy of company presentations. A sampling of actions which have been taken in various countries is given in Country Study V.A.3.

Regardless of the approach taken toward drug company promotion, public drug supply programs must be aware of their own important role in providing drug information.

Locally Written Reference Manuals and Standard Treatment Norms

Locally written drug reference manuals are an integral part of government health programs in Peru, Nigeria, Indonesia, Papua New Guinea, Afghanistan, and numerous other countries. Such manuals are relatively inexpensive to produce and have several advantages over drug industry sources and sources from outside the country in that they are not biased by commercial interest, include only those preparations available in the country, recommend doses which are appropriate for the local population, and include special warnings which are relevant to local genetic, environmental, and epidemiological factors.

Such manuals should include for each drug a minimum of the following items of information:

- medical (non-proprietary or generic) name,
- indications for use,
- dosage forms and doses, with separate doses indicated for adults and children, unless there are separate manuals for the two groups,
- contraindications,
- side-effects or adverse reactions which might be noted,
- special warnings or information to be given to the patient.

Drug reference manuals can be organized alphabetically by drug category (antibiotics, antituberculars, vitamins, etc.), as in Figure V.A.4., alphabetically by medical (generic) name as in Figure V.A.3., or by disease or clinical condition as in Country Study V.A.4. Regardless of the order of information, cross-indexes by drug category, drug name, and clinical use substantially improve the value of the manual for practitioners.

Figure V.A.3. shows sample pages from handbooks used in Papua New Guinea, and Country Study V.A.4. describes the process by which the pediatrics manual was prepared.

Although the content of a drug reference manual is extremely important, the physical characteristics of the manual are equally important determinants of the frequency and manner in which it will be used. Durable booklets which can actually be kept in the pocket are more widely used than are large, shelf-size reference books or flimsy booklets which quickly disintegrate. Larger reference books are useful for hospitals and major health centers, but are less likely to be used by the practicing physician or auxiliary medical worker.

Sometimes consulting physicians and medical school faculty oppose the preparation and distribution of reference manuals, fearing they will lead to "cook book" medicine. This fear seems largely unfounded, and physicians in the most prestigious medical schools in developed countries are writing and promoting such handbooks.

Essential Drugs for Community Health Centers*

Drug	Dosage in mg/kg bw	Dose: Infants-children	Dose: Adults 15 yrs+	Adverse reactions	Contraindications
I. Antipyretics-analgesics					
1. Acetosal Tablet 500 mg		< 1 yr: 10 mg/month, 3-4 times daily 1-3 yrs: 50-60 mg/yr, 3-4 times daily 4-6 yrs: 40-50 mg/yr, 3-4 times daily 7-14 yrs: 30-40 mg/yr, 3-4 times daily	1/2-1 tablet 3-4 times daily	gastric irritation gastric bleeding	gastric ulcer, allergy; Not recommended in DHF and diseases with bleeding tendency.
2. Antalgin tablet 500 mg		< 1 yr: 30-50 mg, 3-4 times daily 1-6 yrs: 50-100 mg, 3-4 times daily 7-14 yrs: 200-300 mg, 3-4 times daily	1/2-1 tablet 3-4 times daily	agranulocytosis	allergy to antalgin
3. Paracetamol tablet 500 mg		< 1 yr: 50 mg, 4 times daily 1-3 yrs: 50-100 mg, 4 times daily 4-6 yrs: 100-200 mg, 4 times daily 7-14 yrs: 250 mg, 4 times daily	1-2 tablets 3-4 times daily		renal disease, hepatitis
4. Phenylbutazone tablet 250 mg		7-14 yrs: initial dose 200-300 mg daily maintenance dose: 100-200 mg daily	1 tablet 3-4 times daily	agranulocytosis	gastric ulcer
II. Antibiotics-Chemotherapeutics					
5. Procain penicillin inj. vial 3,000,000 IU	40,000 IU/kg bw daily	< 1 yr: 100,000-300,000 IU daily (IM) 1-14 yrs: 300,000-600,000 IU per inj.	600,000-2,400,000 IU	allergy anaphylactic shock	allergy to penicillin
6. Streptomycin	Neonate: 20-30 mg/kg infants & children: 40 mg/kg TBC: 50 mg/kg	1-14 yrs: 400-750 mg daily (IM)	1 gr	streptomycin: vestibular disturbances dihydrostreptomycin: - deafness - muscle weakness	allergy vestibular disturbances
7. Benzathine penicillin inj. vial: 2,400,000 IU		600,000-1,200,000 daily (IM)	1,200,000-2,400,000 IU	allergy anaphylactic shock	allergy to penicillin
8. Chloramphenicol caps. 250 mg		neonate: 25 mg/kg daily, divided in 4 doses infants: 2 weeks: 50 mg/kg daily, divided in 4 doses children: 50-100 mg/kg daily, divided in 4 doses	1-2 capsules 2-4 times daily		allergy to antibiotics

*To be used in conjunction with the "Manual on diagnosis and treatment for para-medical personnel".

Country Study V.A.4.

Preparation of a Handbook, "Standard Treatments for Common Illnesses in Papua New Guinea"

The preparation of a manual may be a difficult and lengthy process for one individual, but involvement of a committee of medical practitioners can be a rapid and effective way to produce a manual. The preparation of a pediatric treatment manual in Papua New Guinea occurred in the following way:

1973, November: A national workshop of senior specialists, senior nurses, and senior administrators organized to consider the role of the hospital in health services passed a resolution calling for each of the four major disciplines (pediatrics, adult medicine, surgery, and obstetrics-gynecology) to prepare within 12 months a handbook of standard treatments for not more than 15 of the most common conditions seen in each discipline.

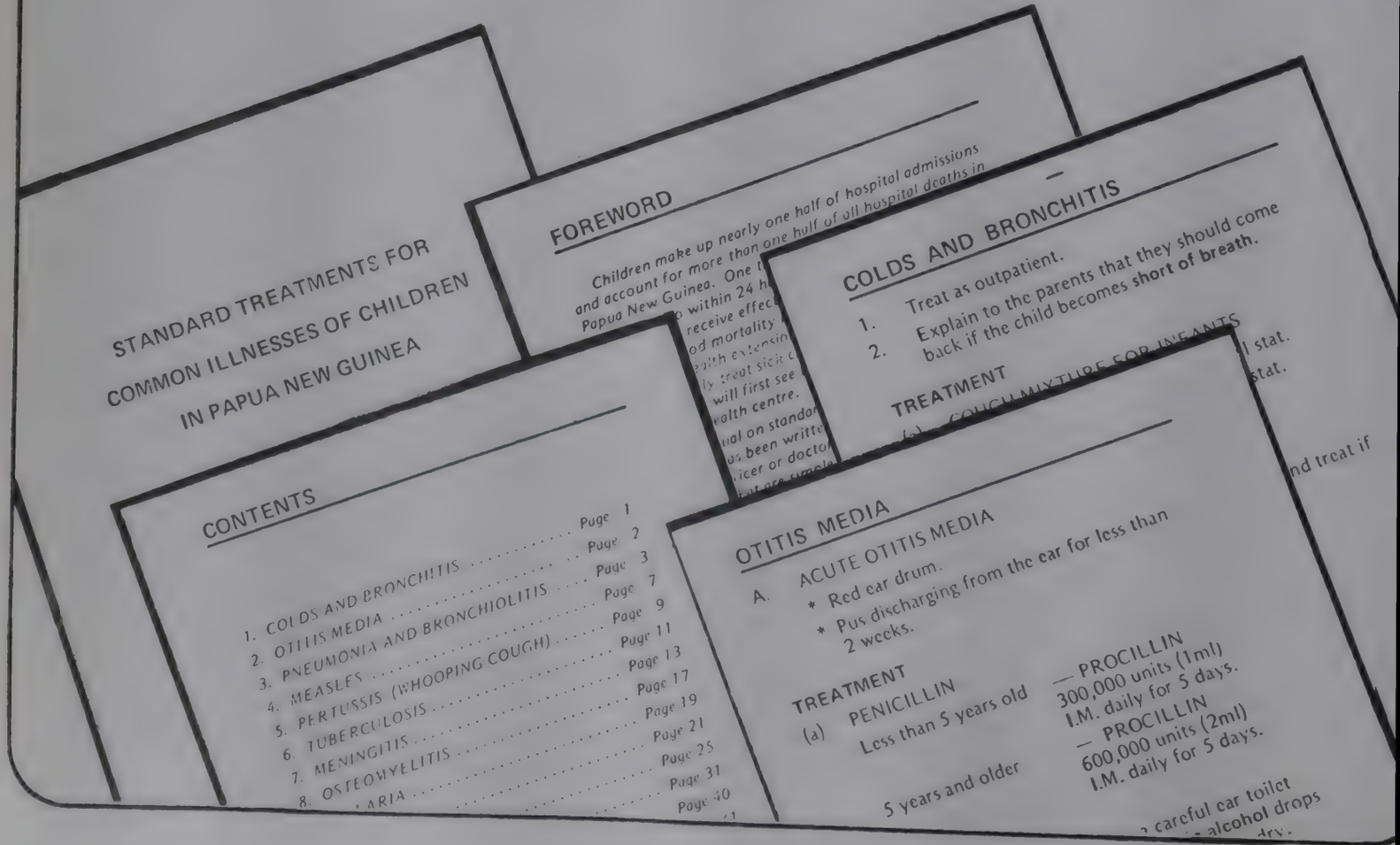
1973, Spring: Chief Pediatrician at the major general hospital circulated for comment pediatrics treatment standards then in use at the general hospital. Comments from the country's pediatricians were collected and then circulated.

1974, August: A two-day workshop was held at a central location to agree on treatment standards for 17 conditions.

1974, December: Pediatrics handbook came off the press.

Although this process was aided by the prior existence of treatment norms at the general hospital, it is illustrative of the type of process which can speed the preparation of a treatment manual. Involvement of the country's pediatricians in the process created support for the manual, which is now used in medical school teaching, on hospital wards, and in the rural health centers and aid posts.

Publication of the pediatrics manual has served several purposes. First, patients -- who may see several different physicians for the same illness or for different episodes of the same illness -- are treated the same way for the same disease each time. This seems to reduce the confusion which patients often feel with changing therapeutic regimens. Second, the handbook is used by pediatric faculty and provides a basis for medical school and medical auxiliary training. Finally, the standardization of treatments contributes to a steadier drug consumption pattern and thereby facilitates procurement and distribution.


STANDARD TREATMENTS FOR COMMON ILLNESSES OF CHILDREN IN PAPUA NEW GUINEA
FOREWORD
Children make up nearly one half of hospital admissions and account for more than one half of all hospital deaths in Papua New Guinea.
CONTENTS
1. COLDS AND BRONCHITIS ..... Page 1
2. OTITIS MEDIA ..... Page 2
3. PNEUMONIA AND BRONCHIOLITIS ..... Page 3
4. MEASLES ..... Page 7
5. PERTUSSIS (WHOOPING COUGH) ..... Page 9
6. TUBERCULOSIS ..... Page 11
7. MENINGITIS ..... Page 13
8. OSTEOMYELITIS ..... Page 17
COLDS AND BRONCHITIS
1. Treat as outpatient.
2. Explain to the parents that they should come back if the child becomes short of breath.
TREATMENT
OTITIS MEDIA
A. ACUTE OTITIS MEDIA
* Red ear drum.
* Pus discharging from the ear for less than 2 weeks.
TREATMENT
(a) PENICILLIN
Less than 5 years old — PROCILLIN 300,000 units (1ml) I.M. daily for 5 days.
5 years and older — PROCILLIN 600,000 units (2ml) I.M. daily for 5 days.

Drug News Periodicals

Drug news periodicals are publications in the form of one- or two-page circulars which appear at irregular intervals, bulletins covering several topics and appearing at regular intervals, and journals organized into several standard types of articles and published on a weekly, monthly, or quarterly basis. Drug news periodicals are intended to provide physicians, pharmacists, nurses, and medical auxiliaries with up-to-date information about drugs.

Who publishes drug news periodicals? In developed countries, most drug news periodicals are published by private associations, medical societies, and national drug control agencies. In addition, international agencies such as WHO publish drug information periodicals. (Appendix II.A.1. contains a listing of some such publications.) In developing countries, drug news is often circulated by the public drug procurement agency. In Peru, Sri Lanka, Papua New Guinea, and elsewhere the public supply programs use these periodicals to communicate with the physicians, pharmacists, and other medical workers who use the supply system.

What kind of information is provided? The content of these periodicals is varied and may include announcements of newly available products with an objective description of their uses, cautions, and side-effects; price comparisons of available drugs meant to increase prescribers' cost consciousness; review articles of drugs of choice for common conditions to encourage proper use of the drugs; introductions of new therapeutic regimens such as the use of oral glucose-electrolyte therapy, rather than intravenous therapy, for mild to moderate dehydration; reminders on storage conditions and notification of changes in storage conditions, such as lessened cold storage requirements for specially prepared vaccines; and publication of quality control and bioavailability test results performed on drugs purchased by the public program; these results are circulated to help increase the confidence of practitioners in the quality of publicly provided drugs.

Where does the information come from? Periodicals published by public drug procurement agencies draw from several different sources. Clinical and pharmaceutical information frequently comes from internationally available periodicals, from the experience of local medical practitioners and pharmacists, and -- whenever it is available -- from local scientific research projects. Pharmaceutical companies are sometimes helpful in obtaining reprints and other information about specific drugs, but summary information prepared solely by a pharmaceutical firm should be used with caution. The periodicals may be written by pharmacists responsible for drug supply, by clinicians from the medical school or medical society, or by specialists in the government service.

Who pays for the publication? Internationally available publications must generally be paid for by the subscriber, although some are available without charge (Appendix II.A.1.). Publications by drug procurement agencies are often paid for out of the agency budget or out of a small mark-up on the drugs which they provide. Since drug news periodicals can usually be printed for a minute fraction of the annual amount spent on drugs, the opinion of some procurement programs is that savings resulting from better drug information can readily offset the cost of the publication.

Drug information circulars, bulletins, and journals cannot be expected to take the place of adequate training and regular supervision of medical practi-

Country Study V.A.5.

The Prescriber: Sri Lanka's National Drug Information Journal

In 1966 the Formulary Committee, which had earlier been charged with the responsibility of curtailing the importation of unnecessary drugs, began a quarterly publication entitled Formulary Notes to provide objective and up-to-date information on drugs to medical practitioners. In 1971, the newly formed state importing monopoly (State Pharmaceutical Corporation, SPC) was formed, and the Formulary Notes became the financial responsibility of the SPC, changing its name to The Prescriber in 1973.

The Prescriber remains the official publication of the National Formulary Committee, whose responsibility it is to approve all drugs imported into or produced within the country. It is edited by a member of the Pharmacology Department of the Faculty of Medicine, and articles are written by clinical pharmacologists, by specialists in medicine, surgery, and pediatrics, and by general practitioners.

Still a quarterly publication, it is sent without charge to the 1750 government physicians, at a discount price to all medical students, and at cost (less than U.S. $1.00 per year) to almost 2500 medical auxiliaries and pharmaceutical importers and manufacturers.

The Prescriber includes the following sections:

1. Feature articles on topics such as:

   - Management of infective diarrhea in children
   - Prescribing in renal disease
   - Treatment of anxiety states
   - Prevention of tetanus

2. Therapeutic Forum, which discusses treatments of choice for conditions such as:

   - Aphthous ulcers
   - Scabies and pediculosis

3. Questions and Answers, which responds to queries raised by physicians and medical auxiliaries on topics such as:

   - "Gaviscon in heartburn"
   - The newer insulins
   - Use of local anesthetics

4. State Pharmaceutical Corporation News, describing:

   - The availability of new drugs
   - Reasons behind dropping a drug from the National Formulary
   - Relative costs of SPC drugs for specific conditions
   - Results from bioavailability tests comparing the products from alternative suppliers.

Although consultant physicians and physicians practicing in either of the country's two medical schools may find The Prescriber too elementary, for many physicians in the periphery and for most medical auxiliaries it is their only regular outside source of drug information. Those who do read the journal find much of the information to be very relevant and useful in their practices. (1978)

tioners. But they should contribute to the continuing education of physicians and medical auxiliaries in more rational use of drugs. Country Study V.A.5. describes the origin and publication procedures of one national drug periodical.

c. Hospital and Regional Drug Committees

Hospital pharmacy and therapeutics committees have existed in developed countries for many decades. Although they were originally charged primarily

with the task of selecting drugs for inclusion in the hospital formulary, in recent years their role has expanded to include greater involvement in establishing prescribing policies. In nationally organized drug distribution systems in developing countries, the role of regional and hospital drug committees is also expanding. There are several important functions which drug committees currently perform in government drug programs or which have been suggested for them, including:

(1) Review of drug requisitions and revision to fit budget allocations

(2) Determination of drugs to be made available to each type of health facility (if this is not determined at the national level)

(3) Development of standard treatment norms for the common illnesses treated in the area

(4) Establishment of prescribing privileges aimed at controlling irrational drug use (e.g., limitation of certain antibiotics to use only under the recommendation of a consultant)

(5) Limitation of the amount dispensed at one time to curb abuse of particular drugs and reduce wastage

(6) Review of antibiotic resistance patterns and revision of guidelines for antibiotic use

(7) Stimulation of drug education activities among hospital staff

(8) General supervision and monitoring of prescribing practices.

d. Prescribing and Dispensing Restrictions

In an effort to play an active role in curbing irrational prescribing and wasteful dispensing of drugs, many public health programs have instituted certain restrictions. Their effectiveness has not always been tested, and, indeed, some restrictions may involve more effort than they are worth. Nevertheless, some limitations on prescribing and dispensing have been found to be useful in countries as diverse as Papua New Guinea, Honduras, Sri Lanka, Indonesia, and Tanzania.

Prescribing Privileges by Level-of-Use

Categorization of available drugs by level-of-use (discussed in Chapter II.A.) has been used to restrict the distribution of drugs both to specific types of health facilities and in accord with the prescriber's level of training. The advantages of organizing drug lists by level-of-use are that (1) medical practitioners at all levels are able to become familiar with a limited number of drugs and to learn how to use these drugs appropriately, (2) educators responsible for pharmacology and therapeutics teaching in medical and medical auxiliary schools are provided with a fairly complete list of drugs with which practitioners must be made familiar, (3) prescribing is limited to those drugs which the practitioner has -- at least in theory --

studied in some detail, (4) drug consumption is more predictable, and, therefore, forecasting of future drug needs somewhat more accurate, and (5) requisition forms can be standardized, further facilitating distribution.

Dispensing Limits

In publicly supported health programs, setting prescription limits has become a common technique to limit wasteful or potentially dangerous dispensing. Examples of this approach follow:

- One Asian country has established a system of 3-day and 5-day limits for all outpatient prescriptions except those for chronic diseases. Most antibiotics are given for 5-day courses, while all other medicines for acute illnesses are limited to 3-day courses.

- In Bolivia, one large rural health program established a system of pre-packaging drugs in unit-of-use plastic bags containing the minimum amount of drug needed for one course of therapy.

- The government-supplied university hospital in one Southeast Asian country puts dispensing limits on items which may be abused, which tend to be prescribed indiscriminately, or which are potentially dangerous. Maximum dispensing quantities are established for codeine, diazepam, vitamin C tablets, and vitamin B complex, among others.

- In the rural health program of a Western Pacific country whose people have not become "drug-minded", there is limited dispensing of drugs for home use. It is felt that most people sick enough to warrant using drugs from their limited supply are sick enough to warrant keeping them near the health post to be sure they actually receive the medicine.

Non-Formulary Prescribing

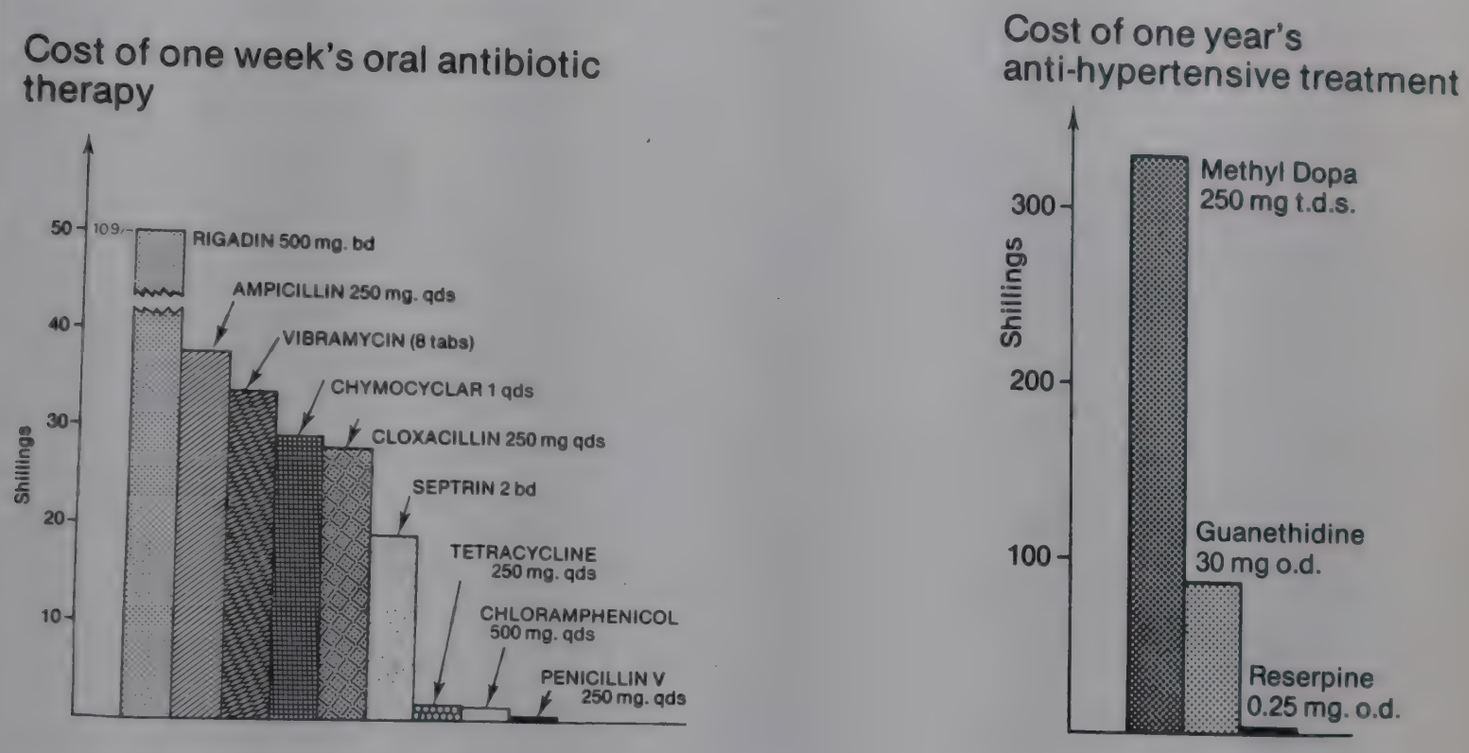
In virtually every hospital or national program with an established formulary or drug list, there is some use of "non-formulary" drugs. In our experience expenditures for non-formulary drugs vary from about five to more than thirty percent of the total drug budget. The amount spent on drugs not officially approved depends on the process for acquiring non-formulary drugs and the ease with which approval is obtained. Programs which allow ready access to non-formulary drugs may have increasing difficulty balancing their drug budgets. Programs which have an established system for reviewing requests for non-formulary drugs and which require documentation of the need for unapproved products maintain closer control over drug utilization.

e. Increasing Cost Consciousness

The first type of prescribing abuse listed in Figure V.A.1. is extravagant prescribing, the use of one drug when a less expensive drug would yield comparabl results. Several different mechanisms have been used to encourage physicians and medical auxiliaries to consider cost in their drug selections:

Figure V.A.5.

Bar Graphs to Increase Cost Consciousness



Source: A.N.P. Speight, 1975.

Cost Bar Graphs -- In the United States, Great Britain, Mozambique, Tanzania, and elsewhere, diagrams showing side-by-side comparisons of prices for alternative drugs have been circulated (e.g., Figure V.A.5.). It is not intended that the practitioners always choose the least expensive drug, but that the graphic presentation of cost comparisons will encourage them to take cost into consideration.

Facility Drug Budgets -- In health programs in which drugs are distributed free or at a nominal charge, specific drug budgets may be allocated to individual districts, hospital areas, or health centers. When annual estimates of drug needs are made or when regular requisitions for drugs are prepared, the expected acquisition cost of the drugs is compared with available funds. If reductions in drug requests are necessary -- and they usually are -- the medical practitioners at the hospital or health center can participate in making the choices. This puts the decision-making closest to the point of drug use. In some settings this level of involvement by the practitioners has helped create a cost-consciousness which makes even their daily prescribing more cost-effective.

Printing Prices in Drug Manuals and on Requisition Forms -- Even when practitioners are not required to conform their drug use to a specific budget, cost consciousness can be promoted by including recent drug prices in therapeutics manuals, drug lists, and other forms which are used in prescribing or requistioning drugs. Alone this measure may accomplish little, but in combina-

Figure V.A.6.

Systematic Approach to Selecting Strategies for Promoting Rational Drug Prescribing

Objective	Current Constraints	Action Alternatives	Required Resources
1. Train medical students in clinical pharmacology and cost-effective drug selection.	•national medical school has no trained clinical pharmacologist	•hire clinical pharmacologist(s) from abroad	•funding for transportation and salary of new position
	•minimal attention paid to side-effects, interactions and contra-indications by faculty when drugs are discussed	•send 1-2 current faculty members on foreign fellowship •send 1-2 recent graduates on foreign fellowship	•funds for 1-2 foreign fellowships (possibly obtainable from WHO or bilateral aid program)
		•obtain a foreign clinical pharmacologist for limited assignment at the medical school to teach current faculty	•funds for transportation and salary for limited term
	•medical faculty not sensitive to cost constraints on public supply of drugs	•meet with faculty to review national health statistics and drug needs in light of budget constraints	•minimal resources for preparation of materials
2. Provide practicing physicians with unbiased, accessible drug information.	•only a few physicians have the time, interest and/or money to subscribe to and read foreign medical journals	•establish a national drug information journal funded by the medical supplies section	•$10,000 per year for publication costs •$1,000 per year for journals and copies of materials •practicing clinicians willing to write articles
	•the national medical society journal has little practical prescribing information	•obtain space in the journal for a regular article on drug prescribing	•practicing clinicians willing to write articles

Objective	Current Constraints	Action Alternatives	Required Resources
2. Provide practicing physicians with unbiased, accessible drug information. (cont'd.)	•drug company representatives provide information which is biased by selection and omission of specific data	•ban drug company representatives from meeting with anyone except national, regional or hospital drug committees	•minimal resources to publicize and enforce the ban
		•establish a committee to review and edit materials used by company representatives	•full-time staff of 5 pharmacists and 3 clerical workers
3. Achieve optimal use of anti-tuberculosis medications.	•treatment regimens not consistent from institution to institution	•limit types of medicines available at different levels of care	•minimal time of medical supplies •staff to select drugs and publisize the limits
	•drugs not properly selected with respect to resistance patterns •resistance increasing •2/3 of patients drop out of treatment within 2 months; half return, but must be restarted on medications	•develop comprehensive tuberculosis control program	•experienced tuberculosis consultant •5-person staff to develop tuberculosis control manual under guidance of consultant •3 full-time trainers to present tuberculosis control program to health workers •$50,000 for additional tuberculosis medication

tion with some of the other measures described in the preceding pages, it may be quite helpful. Physicians and medical auxiliaries need not be required to pick the least expensive drug in all cases, yet the price listing would help them make an inexpensive choice.

3. DEVELOPING A STRATEGY TO PROMOTE RATIONAL DRUG USE

As in other areas of health planning, the promotion of rational drug prescribing requires a systematic approach to selecting strategies. This involves an analysis of the objectives, current constraints, action alternatives, and required resources for facilitating more effective use of drugs. Figure V.A.6. provides an example of such an analysis. Basic planning concepts discussed in Chapter I.C., organizational issues discussed in Chapter VI.A., and training guidelines discussed in Chapter VI.D. are all relevant to developing a program to encourage wise drug use.

Responsibility for implementing activities which promote rational drug use is shared by medical schools, medical auxiliary training programs, Ministry of Health drug control offices, hospitals and other local health facilities, individual practitioners, and the drug supply program. Because of this shared responsibility, efforts to improve prescribing practices are often neglected. Although the directorate of medical logistics or other responsible supply unit does not usually have direct authority over medical training and practice, it can and should work through Ministry of Health and local channels to influence prescribing. Drug supply officials can and should use consumption data to monitor drug use and to stimulate comprehensive efforts to improve prescribing habits.

SUMMARY

Rational drug prescribing requires that the practitioner make an accurate diagnosis, select the best drug from those available, and prescribe the drug in an adequate dose for a sufficient length of time. Choosing the best drug requires a judicious weighing of drug effectiveness, safety, and cost.

Irrational prescribing is common. Categories are:

- extravagant prescribing -- the use of an expensive, usually newer, drug when a less expensive older drug would provide the same effectiveness and safety;
- overprescribing -- the use of drugs for conditions for which they are ineffective;
- incorrect prescribing -- the use of the wrong medication for a condition;

- multiple prescribing -- the unnecessary use of more than one medication for the same condition;

- underprescribing -- the use of drugs at sub-therapeutic dosages in order to conserve medications.

Reasons for irrational prescribing include inadequate training or experience, the practitioner's desire for prestige, promotional activities of drug company representatives, and pressure from patients.

Prescribing practices can be improved through better training of practitioners in pharmacology and therapeutics, and regular supervision of auxiliaries; the availability of current drug information through reference manuals and drug news periodicals; more active involvement of hospital and regional drug committees; prescribing and dispensing restrictions; and the promotion of cost consciousness among prescribers.

CHAPTER V.A. REFERENCES

Blum, R.; Herxheimer, A.; Stenzlaed, C.; and Woodcock, J. (Eds.): Pharmaceuticals and Health Policy. New York: Holmes and Meier, 1981.

Chesterman, C.C.: Tropical Dispensary Handbook. Guildford, United Kingdom: Lutterworth Press, WHO Offprint No. 28, 1960.

Council of Europe Working Party 1975: Abuses of Medicines: II. Prescription Medicines. Council of Europe, European Public Health Community: Drug Intelligence Clinical Pharmacology, 10:94-110, 1976.

Elliot, K.: The Training of Auxiliaries in Health Care. London: International Technology Publications, Ltd., 1975.

Herxheimer, A.: Drug Information: Is there a need for international uniformity? Drugs 8: 321-329, 1974.

Herxheimer, A.: Towards Parity for Therapeutics in Clinical Teaching. The Lancet, II (7996): 1186-1187, November 27, 1976.

Mtulia, I.A.T.: Pharmacology and Therapeutics: A Manual for Medical Assistants and Other Rural Health Workers. Nairobi, Kenya: African Medical and Research Foundation, Rural Health Series 5, 1976.

Rucker, D.T.: Drug Use: Data, Sources and Limitations. Journal of the American Medical Association 230:880-890, 1974.

Speight, A.N.P.: Cost-Effectiveness and Drug Therapy. Tropical Doctor 5(2):89-92, April, 1975.

Wardell, W.M.: Controlling the Use of Therapeutic Drugs: An International Comparison. Washington, D.C.: American Enterprise Institute, Studies in Health Policy, 1978.

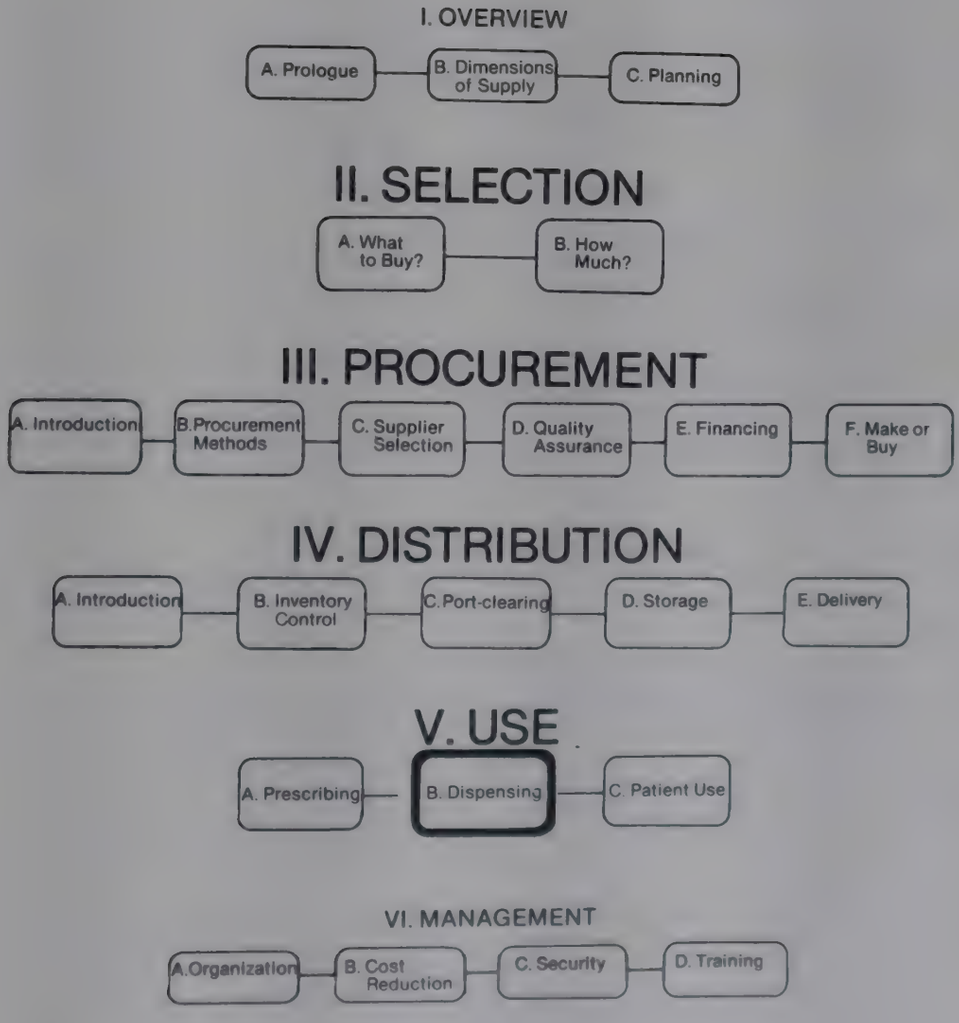
World Health Organization, Regional Committee for the Eastern Mediterranean: Rationality in Supply, Control and Utilization of Drugs. EM/RC24/Technical Discussions/1, Geneva: World Health Organization, 1974.

World Health Organization: Reference Material for Health Auxiliaries and their Teachers. Geneva: World Health Organizaion, 1976.

Wyatt, G.B. and Wyatt, J.L.: Medical Assistant's Manual. Berkshire, United Kingdom: McGraw-Hill International Health Services Series, 1973.

Chapter V.B.

Establishing Good Dispensing Practices



	Page
1. DISPENSING PRACTICES	429
2. STOCK-KEEPING PRACTICES	431
3. PACKAGING FOR PATIENT USE	432
a. Dispensing from Bulk Containers	432
b. Course-of-Therapy Prepackaging	433
4. PHARMACY MANPOWER	438
a. Levels of Pharmacy Personnel	438
b. Use of Pharmacy Auxiliaries	439
c. Training Pharmacy Technicians and Dispensers	440
SUMMARY	442
REFERENCES	443

Establishing Good Dispensing Practices

The dispensing of medications is a basic component of the pharmaceutical logistics system. Without a rational policy and systematic approach to delivering drugs to patients, the pharmaceutical logistics system falls short of its goal of ensuring that essential pharmaceuticals are available to the recipients of a country's health care delivery program.

Dispensing is often overlooked during the development of a pharmaceutical logistics system because it is viewed as being of secondary importance to procurement, inventory control, and distribution. This oversight is unfortunate because poor dispensing practices can undo all of the benefits of careful selection, economical procurement, and effective distribution. All of the resources required to bring a drug to the patient will be wasted if the dispensing process does not ensure that an effective form of the correct drug is delivered to the right patient, in the prescribed dosage and quantity, with clear instructions, and in a package which maintains the potency of the drug.

This chapter outlines the specific principles of dispensing which are essential to the overall functioning of a pharmaceutical logistics system. A number of key policy considerations must be addressed by government officials and health planners to establish the environment within which dispensing functions can be properly performed. Assessment Guide V.B. outlines a number of specific policy considerations.

Although most of this chapter discusses dispensing and compounding as if they were performed only by graduate pharmacists and pharmacy auxiliaries, we recognize that in many settings these tasks are performed by physicians, medical auxiliaries, nurses, or other health workers. Regardless of who is handling the drugs, the principles of sound dispensing practices and adequate packaging should be observed.

1. DISPENSING PRACTICES

The principles of good dispensing fall into five categories: (1) interpreting the request (either by prescription -- written or oral -- or by patient request); (2) retrieval; (3) formulation (compounding, counting, pouring); (4) processing/labeling; and (5) delivery. Since most drugs are ingested, sanitary procedures and common sense should prevail in the drug dispensing environment.

Before dispensing a drug product, the dispenser must clearly know which drug product is being requested. The dispenser must make certain that the drug order, if written, is legible and decipherable or, if orally received, that it is clearly understood. Repeating the drug's name to the patient or physician making an oral request is one way to ensure that the dispenser has correctly perceived the drug desired.

Once the dispenser is satisfied that he knows what is to be dispensed, the retrieval process begins. A commonly accepted practice which guards against the dispensing of incorrect dosage forms is to shelve like dosage forms together

ASSESSMENT GUIDE V.B.
Dispensing Policies and Practices

- What conditions exist at dispensing points? How are drugs handled? How accurately and cleanly are drugs dispensed? How concerned are health officials and health workers about the quality of compounding and dispensing practices?

- How often are patients improperly or ineffectively treated because their medicines have been improperly compounded or dispensed, or because drugs have deteriorated in inadequate packaging?

- At each level in the health care system, who is responsible for the compounding and dispensing of drugs? What training do these individuals have in the principles and practices of drug compounding and dispensing? How much supervision do these individuals receive?

- What types of pharmaceutical training are available in the country? Are there standardized education curricula for pharmacy personnel? Are experience requirements for dispensers spelled out and reasonable, given the numbers and geographical distribution of individuals meeting, or eligible for meeting, these requirements?

- What resources exist to attract sufficiently educated individuals to pursue dispenser training and to what extent can these individuals expect satisfactory remuneration for the services they provide after completing their training?

- Are wages and salaries adequate to effectively dissuade dispensers from engaging in the illegal sale and distribution of pharmaceuticals?

- What kinds of packaging are used to dispense drugs to patients? Is there any mechanized repackaging into course-of-therapy packets? In light of losses from poor packaging and the costs of proper packaging, are there cost-effective alternatives to present packaging methods? Could more expensive containers be recycled?

and physically separate them from other dosage forms. Characteristically, a pharmacy will shelve all oral solid dosage forms (tablets, capsules) together, all oral liquid dosage forms together, and all ophthalmic, topical, or insert dosage forms together. Thus, the likelihood of inadvertently dispensing the wrong dosage form is significantly reduced.

The retrieval process requires that the dispenser carefully read the label on the stock bottle, which includes the product name, strength, dosage form, and expiration date (if any). Since many drug names look alike and/or sound alike, the initial careful reading of the stock drug package label is a critical safeguard against dispensing the wrong drug. Most pharmacists and

well-trained pharmacy auxiliaries will repeat this label reading process two more times during the dispensing activity -- once immediately before the formulation (counting, pouring, compounding) takes place, and once immediately after. Stock drugs which are used should be returned to their original shelf position immediately after formulation. A third label reading is usually performed at this point.

The accurate formulation or preparation of drugs is of interest both to the pharmacy and to the patient. Pre-manufactured drugs, those not requiring compounding, generally require either counting, pouring, or reconstituting. The task of counting must be performed very accurately in that short-counts (dispensing less medication than is ordered) may result in drug therapy failures. In the case of antibiotic therapy, this is particularly critical in that bacterial resistance to subsequent antibiotic therapy may result if initial therapy is prematurely terminated due to a short-count. Conversely, over-counts (dispensing more medication than is ordered), when the price charged is based on the quantity ordered, can be a source of significant financial loss for the pharmacy operation. Repeated over-counts can deplete inventory, and the loss of revenue can adversely affect the cash reserve requirements for maintaining an adequate inventory. Thus, although more time-consuming, it is in the best therapeutic interest of the patient and financial interest of the pharmacy to carefully and accurately count, pour, and reconstitute all medications.

Compounding medications requires the special consideration of mixing order, selection of adjuvants, and the need for special techniques. Once the compounding procedure has been decided on, all necessary materials should be assembled in a single location on the dispensing counter. As each ingredient is used, it should be moved to some other established location on the counter (i.e.,transferred from the left side of a balance, or mortar, to the right side). The use of this technique provides the dispenser with a mechanical check on the introduction of each ingredient. If he is interrupted during the compounding of the medication, there is no doubt as to which ingredients have already been used. After completing the compounding, as all stock drugs are being returned to the shelf, the dispenser should once again read the drug label to verify the accuracy of the compounded medication.

Cross-contamination of drugs can be a serious health problem. Some patients are sensitive (allergic) to very small amounts of some drugs (e.g., penicillin). Utensils and equipment used in the preparation of medications must be thoroughly cleaned to avoid any possibility of contaminating one product with trace amounts of another.

2. STOCK-KEEPING PRACTICES

All drug products should be securely stored in such a manner as to facilitate their ready access, and to reduce excessive deterioration and contamination. As previously pointed out, like dosage forms should be shelved together to reduce the likelihood of dispensing an incorrect dosage form. Stock rotation, using a "first-in/first-out" procedure will help ensure that older stock is used before newer inventory is dispensed. The "first-in/first-out" procedure is easily accomplished by always placing new inventory behind older inventory on the shelf.

Expiration dates may not always agree with the sequence in which drugs are shipped from warehouses. Thus, it is possible that newer inventory -- in terms of when the pharmacy receives the drug -- may possess an earlier expiration date than stock already on hand. If the expiration date of the newly received product is significantly earlier than that of existing stock -- 6 months or more -- and the drug is routinely dispensed, it may be prudent to begin using the newly received stock prior to exhausting the existing stock. Under no circumstances should inventory be dispensed when the expiration date has been exceeded by more than one year (or less, depending on storage conditions and the chemical nature of the drug product).

Deterioration of drugs can be brought about by a number of factors, the most critical of which are heat, moisture, and light. In all cases, adequate ventilation should be assured in storage areas. Drugs requiring cold conditions (below 10°C) should be refrigerated. Dehumidification, although desirable in excessively humid regions, is often impractical and unfeasible. Therefore, to reduce deterioration due to moisture, drug containers should be tightly closed and moisture absorbing dessicants placed inside. Many drugs, particularly liquids, are photo- (light) sensitive, and require shielding. Where possible, these drugs should be stored and dispensed in light-resistant containers such as amber bottles. The dispenser should be alert to physical signs of drug deterioration such as changes in consistency, color, and smell.

3. PACKAGING FOR PATIENT USE

In all but the most basic systems, drugs are dispensed to patients in some form of container. The type of container used may affect the quality of the medicine at the time it is consumed. It can also have an important impact on the patient's image of the health system and his faith in the medicine (e.g., shoddy packaging connotes an unreliable system and ineffective medicine); it may thus affect the correctness with which the medicine is used.

Medicines can be dispensed to patients in one of two ways: in individual packets filled on the spot by the dispenser from bulk containers, or in course-of-therapy packets which are filled and labeled in advance with standard drug quantities.

a. Dispensing from Bulk Containers

Traditionally, drugs are bought and distributed in bulk containers and, from these, dispensed into smaller containers according to individual prescriptions. This system depends on correct drug identification and measurement by the dispenser, adequate labeling of the individual container, and the availability of individual containers which are suitable to the environment.

Accurate counts of solid dosage forms and measures of liquid dosage forms can be easily achieved by following principles of good dispensing practice. Solid dosage forms (tablets and capsules) should be placed on counting trays with a receptacle for catching the counted drug and a pouring spout for returning the excess drug to its stock container. Count accuracy is increased when a smaller number of drug units is counted together (i.e., counting by 5's

is more accurate than counting by 10's). Efficiency and accuracy are best achieved when no more than 5 drug units (tablets, capsules) are counted together at a time.

Liquid dosage forms and liquids for reconstitution should always be measured using a graduated measuring flask of a size consistent with the quantity of liquid to be dispensed. For example, if an ophthalmic preparation requires 5 cc of distilled water for reconstitution, a 500 cc graduated cylinder should not be used. The error factor for this measuring device may be as much as 25 cc, thus permitting a possible overdilution of 250%. As a rule, the volume of a measuring instrument should not exceed the volume of liquid to be measured by a factor of 10. The dispenser must remember that in reading all liquid measurements, the bottom of the meniscus should be used for establishing the volume measurement.

Labeling individual containers and packets is time-consuming, but essential for correct drug use. In busy outpatient practices labels are sometimes reduced to a series of numbers, such as "2 x 3 x 5" (two tablets three times a day for five days). This type of labeling inevitably leads to improper drug use. Prepared labels may add expense to the system, but may result in long-run savings in health care costs, by saving the dispenser time and increasing proper drug use. Preprinted symbolic labels have proven useful and are discussed in detail in the following chapter (Chapter V.C.).

Programs faced with limited funding and seemingly overwhelming demands for medicines often "save" by using scraps of paper or other used material for packaging drugs. The visible savings from not buying packaging materials must be weighed against the hidden costs of wasted drugs and inadequate therapy when drugs dispensed in this way deteriorate or are lost. Figure V.B.1. lists available packaging materials and indicates which materials are desirable or acceptable and which materials are undesirable.

Although plastic drug vials or pasteboard containers are expensive and often unobtainable in the remote regions of developing countries, they provide the maximum protection for the drug product after it is dispensed to the patient. Less costly alternative containers include envelopes, bags, or folded paper. In choosing a container, the dispenser should be alert to potential contamination or deterioration. Absorbent materials such as cotton placed in contact with the drug may absorb some of the active ingredient, thus reducing its strength. Similarly, placing the drugs into previously used materials (such as newspapers) may contaminate the drug and cause an ill-effect to the patient. At the least, drug products should be wrapped in clean "glycine"-type paper prior to placing into alternative dispensing containers.

Program managers are encouraged to consider the trade-offs involved when their budgeting process leads to the use of inadequate labels or packages.

b. Course-of-Therapy Prepackaging

An alternative to dispensing from bulk containers is to have medicines prepackaged in sealed plastic bags, each of which contains a complete course-of-treatment for that drug, as established by Standard Norms (see Chapter II.B.). For example, if the norm for treating streptococcal pharyngitis is

Figure V.B.1.

Packaging Materials for Drug Dispensing

CATEGORY OF PACKAGING*	PACKAGE CHARACTERISTICS	EXAMPLES
A. Tablets/Capsules		
Desirable	Clean, dry, plastic or glass container with tightly sealing cap or seal.	Blister Packages; Plastic Sachets; Tightly Sealing Plastic or Glass Containers with Screw or Snap Cap
Acceptable	Clean, dry container which provides protection from dirt and moisture.	Zip-lock Plastic Bags; Glycine Paper; Hinged-lid Boxes; Sifter-top Boxes; Tight-top Tins
Undesirable	Unclean absorbent paper, cotton, cardboard containers with no provision for closure	Unsealed Plastic Bags; Paper Bags; Newspaper or other printed paper
B. Liquids (Oral & Topical)		
Desirable	Clean, dry, light-resistant glass container with tightly sealing cap.	Amber Bottle with Screw Cap; Opaque Bottle with Screw Cap
Acceptable	Clean, dry plastic/glass container with tight-fitting cap.	Glass or Plastic Bottle with Tight-Fitting Cap
Undesirable	Unclean paper, cardboard, metallic, or plastic (not formed) container with no provision for closure.	Previously Used Liquid-Containing Cartons; Plastic-Lined Paper Bags; Plastic Bags
C. Liquids (Otic & Ophthalmic)		
Desirable	Clean (preferably sterile) light-resistant glass or plastic container with a dropper incorporated into a tightly sealing cap, or dropper fixed top with protective sleeve.	Amber Dropper Bottle; Opaque Plastic Dropper Bottle
Acceptable	Clean, dry plastic/glass container with tight-fitting cap and a clean plastic/glass dropper (separate).	Glass or Plastic Bottle with Tight-Fitting Cap; Glass or Plastic Dropper with a Protective Container (cardboard, zip-lock, plastic, or paper)
Undesirable	Unclean paper, cardboard, metallic, or plastic (not formed) container and no provision for closure.	Previously Used Liquid-Containing Cartons; Plastic-Lined Paper Bags; Plastic Bags
D. Creams/Ointments		
Desirable	Clean, glass or porcelain wide-mouth jar with tightly fitting lid or collapsible plastic/metal tube.	Wide-Mouth Jar with Well-Closed Lid; Cream/Ointment Tube with Cap
Acceptable	Clean, glass or porcelain jar with lid.	Glass or Porcelain Jar
Undesirable	Unclean paper, cardboard, metallic, or plastic (not formed) container and no provision for closure.	Previously Used Liquid-Containing Cartons; Plastic-Lined Paper Bags; Plastic Bags

* Desirable -- Packagings should meet the listed requirements for a period greater than 30 days.
Acceptable -- Packagings should meet the listed requirements for up to 30 days.
Undesirable -- Packagings provide no protection from dirt, moisture, etc., thus permitting rapid deterioration or contamination.

Penicillin G, 400,000 units three times a day for ten days, then each prepackaged course of therapy will contain thirty tablets.

The plastic package will have two other important parts -- a label giving the drug's name, its indications, and directions; and a receipt that has the name of the drug printed on it and space for filling out the patient's name and date. The label greatly facilitates patient understanding of the directions and gives him a written reminder. Experience has shown that even patients who cannot read almost always have access to someone who can within their own village. In areas of high illiteracy, it is also possible to use symbolic labeling for instructions (see Chapter V.C.). The receipt for the medication is detached during dispensing and kept for inventory control purposes. The number of receipts plus the number of undispensed plastic bags should equal the number of bags given to a dispenser. This simplifies drug accounting and reduces drug losses.

Benefits

There are many advantages to course-of-therapy prepackaging, including the following:

(1) Safer, easier, and faster distribution of drugs with less room for error. This frees the dispenser from routine counting chores to have more communication with the patient.

(2) Less deterioration of drugs due to adverse environmental conditions. Prepackaged drugs may remain unchanged for up to two years while bulk drugs are likely to deteriorate much earlier due to high heat and humidity.

(3) Easier and more accurate recording of inventory with better control over drug supplies and more accurate consumption data.

(4) Improved credibility among users, due to the attractiveness and cleanliness of the package, which can approach that of commerical drugs.

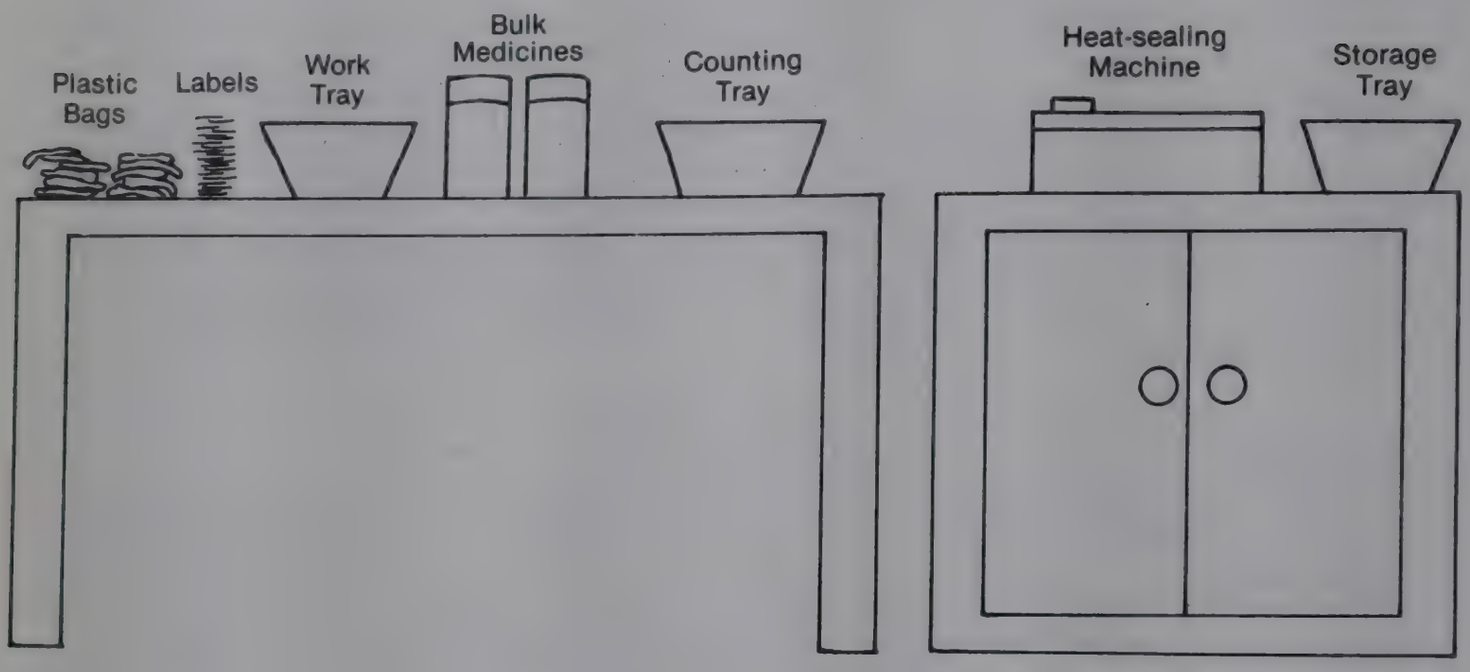
(5) Increased likelihood that patients will take the drugs as prescribed for the proper period of time, and decreased tendency to prescribe only partial therapeutic doses.

(6) Greatly facilitated storage and distribution, by minimizing the amount of bulk stock tied up in peripheral health centers.

(7) More accurate and efficient prescribing by all health workers, as they have available the exact amount of drugs needed for course-of-therapy; less writing required from lower level health workers.

The disadvantages of this system are small compared to the benefits. Equipment must be made or purchased, staff need to be trained, and space must be located. These are discussed in detail in the next section. There has been some physician resistance to this system, and some feelings of loss of

Figure V.B.2.
Drug Prepackaging Operation



independence. This usually disappears after some experience is gained with the system and the actual benefits are observed.

Equipment and Methodology

Figure V.B.2. depicts the basic layout for a simple prepackaging operation. The following supplies and equipment are needed:

(1) Plastic bags -- These often come in long plastic sleeves in various widths, sold either in standard lengths or by weight. They can be purchased locally in many countries.

(2) Heat sealing machine mounted on a table -- This can be purchased commercially* or made locally, as has been done by some programs. The principle involves a heated device 1/8" wide that produces a seal on the plastic sleeve to make a bag. The bag is then filled, and the open end is likewise sealed to complete the package.

(3) Labels -- Preprinted with name of drug, dosage, and instructions for use (both written and symbolic). In more sophisticated systems these can be imprinted directly on the plastic bags using colored ink, including a logo or some identifier for the health program.

(4) Receipts -- Preprinted with name of drug and dose, and blank space for writing in patient's name and date.

---

* The Vertrod Thermal Impulse Heat Sealing Machine with foot pedal, available from Vertrod, Inc., 2037 Utica Avenue, Brooklyn, New York, 11234.

(5) Staple machine and staples -- to attach receipt.

(6) Work table

(7) Work trays -- for bulk drugs.

(8) Storage trays -- for finished packets.

(9) Tablet/capsule counting boards -- These can be made locally from wood where the exact number of holes needed for each drug is drilled into the top, in the correct size and shape.

(10) Counting trays

(11) Funnel

(12) Cleaning equipment

In the prepackage operation the technician performs six basic steps:

(1) He sets aside the correct number of plastic bags. If purchased in sleeves, they must be made up in advance.

(2) He inserts the labels and places the bags with labels into a tray.

(3) He empties the tablets or capsules into the counting tray.

(4) He counts out the correct number by scooping the counting board tray for that drug into the tray and wipes off the excess, pours these drugs through a large funnel into the bag, and places the filled bags in a storage tray.

(5) He seals the bags and places them in a storage tray.

(6) He then attaches a receipt to the bags and prepares them for storage or shipment.

This is the simplest manual operation available, and can be done at any level -- central, district, or local. This operation can provide drugs for a small project or for a whole national program. Where more resources are available, the operation can be automated and the output increased. However, this increases capital investment costs, and maintenance can be a problem; the trade-offs need to be calculated for each country. Country Study III.F.1. describes in detail the costs determined in a feasibility study by one large government program starting on a prepackaging system.

In countries where this operation is done manually, the costs amount to U.S.$0.005/bag, including machinery and personnel (excluding the cost of the drug). Considering the benefits, countries who have investigated this system feel the cost-benefit ratio can also be applied to liquids and creams as long as the appropriately sized containers are available.

It is important to stress that course-of-therapy is different from commercial unit-dose packaging. In unit dose systems, individual tablets or capsules are prepackaged at the factory in plastic sleeves or in blister-foil

packages. These have the advantages of protection from environmental deterioration and ease of dispensing, but unless these unit-dose packages are themselves packaged in a box with complete instructions, the advantage of improving patient compliance is lost. The combined costs of foil packages and boxes increases the costs of unit-dose packaging to 20 times that of course-of-therapy, and requires more complicated machinery that is difficult to maintain.

Care must be taken to ensure that course-of-therapy bags are properly sealed. Incorrect use of the sealer, poor maintenance of the equipment, or the wrong type of plastic can all result in an inadequate seal and early drug deterioration or contamination. Moisture-sensitive test materials are available which can be sealed into the bags; if the test material changes color within a specified period of time, it indicates that the seal has been inadequate

Results

Prepackaged course-of-therapy operations have been successfully implemented in situations as diverse as a national rural health program in Afghanistan and a regional project in Bolivia. In Afghanistan, after this operation had been implemented, a sample of patients and service providers were interviewed to obtain their responses to the system. Generally, acceptability of the packages was high among both patients and providers. Providers especially liked the time saved in dispensing and freed up for patient care. Of interest for patient compliance is the fact that only 25% of patients understood how to take their medicine correctly when they left the health center, but 100% were able to find someone in the village who could explain the label to them. With the results of this survey, the Ministry of Health concluded that the costs were reasonable and the benefits substantial, and made the commitment to implement this on a national scale.

4. PHARMACY MANPOWER

Drugs are commonly dispensed by a pharmacist or pharmacy auxiliary, but in many countries physicians, nurses, physician assistants, and medical auxiliaries also participate in the dispensing process.

The use of pharmacists and auxiliary personnel in drug dispensing activities varies greatly from country to country. For example, in one Asian country, there are only three bachelor-level pharmacists for a population of 15 million. The majority of private "pharmacists" have 12-13 years of public schooling and a one-year course in pharmacy at the national university. Dispensers have an elementary school education and attend a six-month training program in a hospital pharmacy. Country Study V.B.1. provides other examples of the use of pharmacy personnel.

a. Levels of Pharmacy Personnel

In many countries, a small nucleus of qualified and experienced pharmacists are utilized in managerial roles while auxiliary staff with non-traditional pharmacy backgrounds perform routine dispensing functions. Commonly, there

Country Study V.B.1.

Pharmacy Personnel in Selected Countries

Papua New Guinea -- The dispenser training program was inatiated to fill a void in the training of nationals in pharmaceutical services. Dispenser candidates must have at least 10 years of education with credits in English, science, and math. The curriculum consists of 18 months of classroom and laboratory work, 15 months of pharmacist-supervised on-the-job training split evenly between work in a regional hospital and work in a regional drug supply center, and 3 months of guided review in preparation for the final qualifying exam. The current emphasis of the program is on training students to prepare a variety of solutions, mixtures, and creams, and to appropriately handle and dispense all types of medicines. Dispensers act as supply officers for many hospitals, assist the pharmacists in drug formulation, and, in some areas, periodically visit aid posts to review stock levels and advise rural health workers on ordering and stock-keeping. (1978)

Jamaica -- In the 1950's the profession of pharmacy lost much of its status as pharmacists were gradually restricted to dispensing. In 1961, in order to upgrade the profession, and to attract students into pharmacy, a formal course of instruction was introduced. Students were admitted after ten years of formal education, preferably with credits in English, mathematics, and a science subject.

The first year of instruction was essentially a pre-pharmacy year devoted to physics, biology, chemistry, and English. The second year included the technical subjects of pharmaceutics and pharmacological chemistry. The third year contained a six-month study of pharmacognosy, physiology, pharmacology, and forensic pharmacy. A college diploma was awarded to those who passed all final examinations, but before a license to practice was conferred by the statutory pharmacy board, it was necessary to complete a six-month preregistration appointment at an approved pharmacy.

In developing training in pharmacy, consideration was given to the following factors: (1) Jamaica could not produce sufficient numbers of pharmacists at a professional level; (2) practical pharmacists were required; (3) reciprocity with the United Kingdom was not a cardinal factor; (4) the level of training should be adjusted to sound local professional requirements; (5) the need for a graduate course was not yet apparent; and (6) there was not an adequate supply of students at the necessary level of general education to support a graduate course. (From Fendall, 1972)

Norway -- Three levels of pharmacy personnel exist in Norway: Pharmacists, Prescriptionists, and Pharmacy Technicians. Pharmacists are graduates of a five year university program and are ultimately responsible for all dispensing. Prescriptionists are graduates of a 3 year program following secondary school. They are trained to perform all aspects of commercial and hospital pharmacy. Pharmacy Technicians complete a one year training program which allows them to dispense drugs. They generally do not compound preparations and their work is supposed to be checked by a Prescriptionist or a Pharmacist. (1978)

are three levels of pharmacy personnel. The bachelor-level or graduate pharmacist has 15 to 16 years of formal education and serves in the higher posts in universities and training centers, in pharmaceutical supply management, and in large hospitals. The mid-level pharmacy technician, sometimes called a pharmaceutical assistant or prescriptionist, is trained in all aspects of pharmaceutical science, therapeutics, drug compounding, drug dispensing, and pharmacy management. In some settings training in many of the technical aspects of industrial pharmacy is included. The third level is the dispenser, who is trained in the basics of filling prescriptions and maintaining drug stocks.

b. Use of Pharmacy Auxiliaries

The role of pharmacy personnel varies greatly from country to country. Some countries have established dispenser training programs with the expectation that dispensers will fill prescriptions at all but the smallest health facilities. In other countries, pharmacy personnel, including dispensers, are

Country Study V.B.2.

Dispenser Productivity in Southeast Asia

In one Southeast Asian country where the Ministry of Health Pharmacy Division maintains close control over pharmaceutical supply services in all Ministry of Health facilities throughout the country, government-trained dispensers constitute a major portion of the Ministry's pharmacy manpower.

Started in 1957 and expanded in 1964 and again in 1973, the dispenser training program is now intended to graduate about 100 students per year. Applicants must have completed eleven years of primary and secondary education, including training in science, math, English, and the national language. Students are selected from a pool of well over 1,000 applications per year. The three year curriculum includes one year of formal course work followed by two years of practical training. The faculty consists of two graduate pharmacists, five dispenser graduates, and several assistants. Dispensers assist graduate pharmacists in providing hospital pharmacy services and they are trained to handle all aspects of outpatient pharmacy. The goal of the Ministry of Health is to have about one dispenser for every 100 inpatient beds and to have at least one dispenser in all but the smallest outpatient facilities. It is expected that one dispenser can handle a workload of 50 outpatients per day.

The following are typical staffing and patient volume patterns found at various health facilities:

Type of Facility	Dispensing Staff	Patients per Day	Patients per Day per Staff Member
Teaching Hospital Outpatient Department	3 pharmacists 17 dispensers	1,800	90
Urban Health Center	2 dispensers	100-150	50-75
District Hospital	1 pharmacist 3 dispensers 1 storekeeper 1 dispenser-trainee + hospital attendants	180-320	30-55 (+ all Inpatients)
Health Center (Small Town)	1 dispenser	100-120	100-120

(1978)

located only at large hospitals. Dispensing at smaller hospitals, at health centers, and at aid posts is left to the medical practitioners. In part, this is a question of resources: putting a dispenser in each health center would be a costly luxury in a program which could not yet provide medical auxiliaries and village health workers. But it is also a question of priorities: the value of specially trained pharmacy auxiliaries and dispensers is not always recognized. In our experience, the presence at health facilities of personnel specifically trained for drug handling results in improved handling, more efficient use of limited drugs, and less waste.

Country Study V.B.2. illustrates the policy toward pharmacy auxiliaries in one Ministry of Health involved in distributing over U.S.$10 million worth of drugs each year.

c. Training Pharmacy Technicians and Dispensers

Programs for training pharmacy technicians and dispensers exist in many countries today. Generally, these programs have modest enrollment requirements, and provide a limited curriculum designed to familiarize the student with basic principles of pharmacy and dispensing practices.

Country Study V.B.3.

Pharmacy Training in Tanzania

Tanzania currently has three levels of pharmacy personnel: (1) Bachelors of Pharmacy, (2) Pharmaceutical Assistants, and (3) Dispensing Auxiliaries.

Bachelors of Pharmacy serve as the senior pharmacists in government hospitals and operate commercial pharmacies. They are trained in the Pharmacy Department of the national Muhimbili Medical School, following a fairly standard course for graduate pharmacy training. In contrast, Pharmaceutical Assistants and Dispensing Auxiliaries are trained in programs developed to fit specific national manpower needs.

In 1972, to combat the extreme shortage of people with pharmacy training at the government's district and regional hospital pharmacies, a separate School of Pharmacy was established at Muhimbili Hospital. The faculty consists of a full-time director, a pharmacist paid by the Health Ministry, four volunteer pharmacists from overseas, and one to three pharmacy assistants, who are graduates of the Pharmaceutical Assistant program or bachelor students in the Pharmacy Department. At any one time there are approximately 15 to 18 students in the one-year Dispensing Auxiliary program and 50 to 60 students in the three-year Pharmaceutical Assistants program (18-20 per class).

Pharmaceutical Assistants -- Candidates must have completed at least ten years of formal schooling, with good grades in chemistry, physics, biology, and mathematics. Beginning near the end of the second year, there is a six month field work block during which students are placed in hospital pharmacies under the supervision of the pharmacist or Pharmaceutical Assistant in charge. Emphasis during this field work is on compounding, dispensing, and stock control. The syllabus for the three-year program consists of:

FIRST YEAR
- Hygiene (water-borne disease, pharmacy cleanliness, etc.)
- Anatomy and Physiology
- Medical Stores Control
- Pharmaceutics (theory and practice of drug preparation and preservation)
- Inorganic Chemistry

SECOND YEAR
- Pharmaceutics (theory and practical)
- Pharmacognosy (study of naturally occurring medicaments)
- Elementary Organic Chemistry
- Elementary Pharmacology (study of therapeutic use of drugs)
- Microbiology (broth and stain mixing, etc.)

THIRD YEAR
- Pharmaceutics (largely practical)
- Forensic Pharmacy (laws of pharmacy control, etc.)
- Pharmacology
- Practical Hospital Dispensing

Graduates of the program assist bachelors of pharmacy in regional and national hospitals and often serve as the sole pharmacist. They are responsible for compounding preparations not supplied in finished dose form, for dispensing all items to inpatient wards and outpatient facilities, and for stock-keeping. They are not usually charged with preparation of injectable drugs. Pharmaceutical Assistants also help staff the government pharmaceutical production plant, where they have supervisory responsibility.

Dispensing Auxiliaries -- To be eligible for the eleven month program, candidates must have at least an elementary school education and have worked in a hospital at some level. The curriculum consists of: Pharmaceutics (theory and practice), Pharmacology, Calculations (dosage, pill count, basic mathematics, etc.), Forensic Pharmacy, and Medical Stores Control. During the last six months, there are at least four hours per week of in-hospital and dispensary supervised practicum.

Dispensing Auxiliaries are expected to be able to perform the basic tasks of compounding and dispensing necessary to run the pharmacy of a small hospital, but are not expected to prepare injectable medicaments or other items requiring special skill or knowledge. At regional and national facilities they serve under Pharmaceutical Assistants and Pharmacists.

An important part of stimulating competence and motivation in any profession is the establishment of adequate compensation and realistic opportunities for advancement. For pharmacy personnel, the salary for Dispensing Auxiliaries begins at about 1 1/2 times the urban minimum wage and increases for Pharmaceutical Assistants Grade II and for Pharmaceutical Assistants Grade I, when it reaches 3 times the minimum wage. Dispensers can be upgraded to Pharmaceutical Assistants by taking a special course or by passing a special exam after having been in service for a sufficient length of time.

As with many health workers, Pharmaceutical Assistants and Dispensing Auxiliaries in practice tend to become less careful than when they were in training, and, in addition, they frequently come under social or financial pressure for unauthorized dispensing. Continued supervision and careful placement of personnel is important in combatting these difficulties.

Although the programs at the School of Pharmacy are relatively new, they are already making an important contribution to improving the handling and storage of drugs and in the safety and accuracy of drug dispensing. (1978)

In Guatemala, dispensers are trained for a minimum of five years through an apprenticeship program in specially licensed pharmacies. Senegal uses graduates of a two-year technical training program in nursing as dispensers after the completion of supplemental pharmacy training leading to the title "infirmier specialiste en pharmacie". In Thailand, nurses are given supplementary pharmacy training of three or four months which, together with the nurses' training, qualifies them to dispense pharmaceuticals in rural hospitals. Country Study V.B.3. describes the training programs in Tanzania.

Although there is no standardized pharmacy technician curriculum, most training programs cover the essential core subjects related to dispensing. These subject areas include (1) familiarity with drug products and drug references, (2) weights and measures, (3) compounding techniques, and (4) practical training (apprenticeship).

SUMMARY

Good dispensing ensures that an effective form of the correct drug is delivered to the right patient, in the prescribed dosage and quantity, with clear instructions, and in a package which maintains the potency of the drug.

There are 5 steps to good dispensing:

(1) interpreting the request
(2) retrieval
(3) formulation (compounding, counting, pouring)
(4) processing/labeling
(5) delivery.

Care should be taken to read labels accurately, to count and measure carefully, and to guard against cross-contamination of drugs by thoroughly cleaning utensils and equipment.

Stock-keeping practices should include:

- shelving like dosage forms together
- rotating stock, using a "first in/first out" procedure, with
- new inventory placed behind older inventory on shelf
- protection from heat, moisture, and light
- adequate ventilation.

Packaging may affect:

- the quality of the medicine at the time it is consumed
- patient's image of the health system
- patient's faith in the medicine.

Packaging should protect the drug and be accurately labeled.

Medicines are dispensed from bulk containers or in course-of-therapy packets filled and labeled in advance. Course-of-therapy prepackaging has important advantages which frequently justify the small additional expense involved:

(1) safer, easier, and faster dispensing
(2) less deterioration of drugs
(3) easier and more accurate recording of inventory
(4) improved credibility among users, due to appearance
(5) increased patient compliance
(6) easier storage and distribution
(7) more rational and more efficient prescribing.

Prepackaging operation requires equipment, trained staff, and space.

There are 3 common levels of pharmacy personnel: graduate pharmacist, pharmacy technicians, and dispensers. Special training for drug handling increases efficiency of dispensing practices.

CHAPTER V.B. REFERENCES*

American Society of Hospital Pharmacists (ASHP): Training Guidelines for Hospital Pharmacy Supportive Personnel. Washington, D.C.: American Society of Hospital Pharmacists, 1976.

ASHP: Training Hospital Pharmacy Supportive Personnel: A Compilation of Selected Reprints on Hospital Pharmacy Technician Training. Washington, D.C.: American Society of Hospital Pharmacists, 1977.

ASHP: ASHP Guidelines for Single Unit and Unit Dose Packaging of Drugs. American Journal of Hospital Pharmacists, June 1977.

Cooper, J.: Plastic Containers for Pharmaceuticals, Testing and Control. Geneva: World Health Organization, 1974.

Durgin, J.M., Hanan, Z.I., and Ward, C.O.: Pharmacy Technicians' Manual. 2nd Edition. Saint Louis, MO: The C.V. Mosby Company, 1978.

Fendall, N.R.E.: Auxiliaries and Primary Medical Care: Programs in Developing Countries. Baltimore, MD: Johns Hopkins, 1972. Chapter X, Pharmacy and the Auxiliary.

Labrecque, J.: Regional Service Center Provides Prepackaged Medications, Journal of the American Hospital Association, May 1, 1976.

Maganu, E.T., et al: A System for Drug Administration, Tropical Doctor, Volume 8, July, 1978.

Martin, E.W.: Pharmaceutical Dispensing. Easton, PA: Mack Publishing Company, 1966.

---

* (See Appendix II.A.1. for drug information sources.)

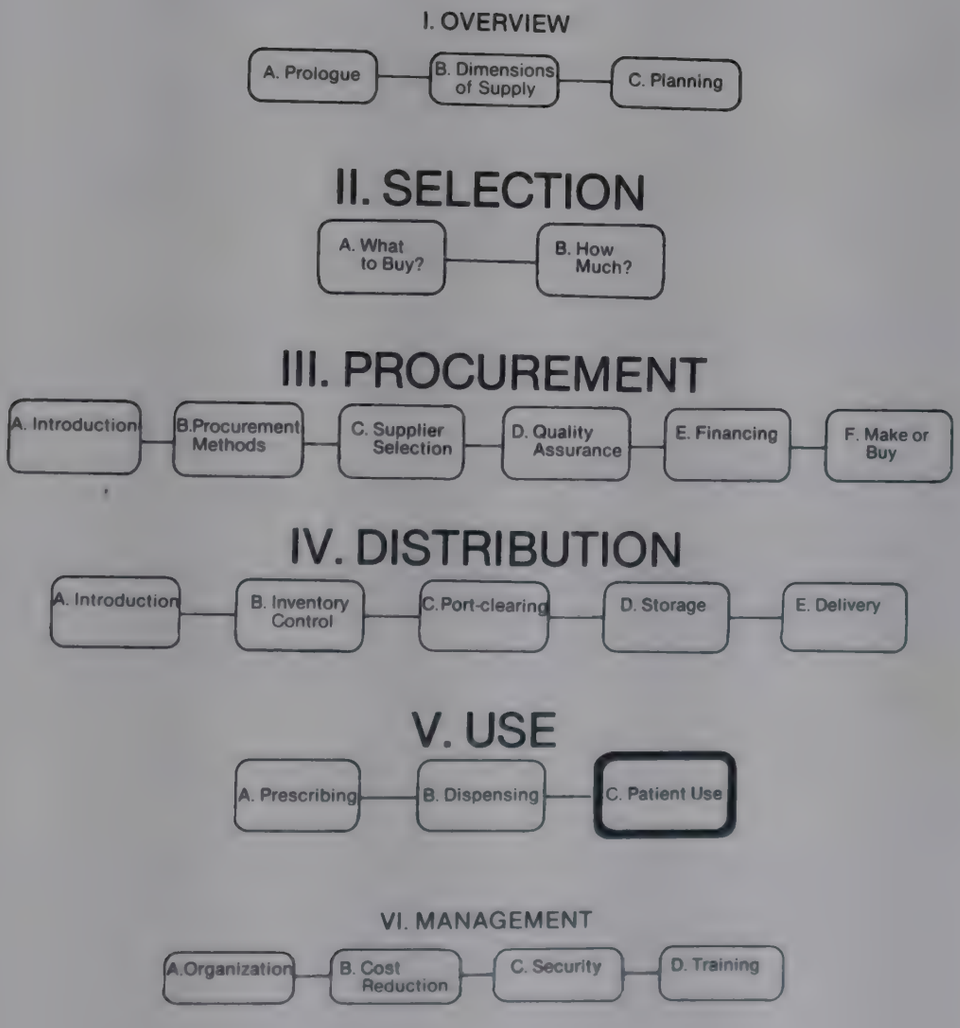
Ross, C.F.: Packaging of Pharmaceuticals. London, England: Institute of Packaging, Newnes-Butterworths, 1975.

Smith, H.A.: Principles and Methods of Pharmacy Management. Philadelphia, PA: Lea & Febiger, 1975.

UNIDO: Information Sources on the Packaging Industry. New York: United Nations Industrial Development Organization, 1977.

Chapter V.C.

Encouraging Appropriate Use by Patients



	Page
1. COMPLIANCE TO DRUG REGIMEN	447
a. Illness	447
b. Patient	448
c. Prescriber	448
d. Medication	449
e. Structure of Services	449
f. Culture	449
2. PRESCRIBER'S ROLE IN PATIENT EDUCATION	450
3. DISPENSER'S ROLE IN PATIENT EDUCATION	452
4. PACKAGING AND LABELING	454
Symbolic Labeling	
5. COMMUNITY EDUCATION ACTIVITIES	454
a. Mass Media	456
b. Institutional Education Efforts	456
c. Personal Contact	457
SUMMARY	457
REFERENCES	459

Encouraging Appropriate Use by Patients

When all the activities outlined in previous sections have been performed, then adequate quantities of appropriate drugs will be present at each health service location, and doctors, nurses, auxiliaries, community health workers and other providers will have been trained in their use. The next question is, "How do we assure that patients will take the drugs appropriately as prescribed?" If the patient does not take the proper drug in appropriate dosages at the right times, the best functioning logistics system in the world will still have little impact on health problems. This section discusses some of the issues involved in encouraging appropriate drug use by patients.

1. COMPLIANCE TO DRUG REGIMEN

Compliance is the degree to which patients adhere to medical advice and take medicines as directed. Most studies on drug compliance in outpatient settings in developed countries show an average of 50% compliance; that is, only one-half of patients take medicines as prescribed. The most common error is taking the wrong dose or taking it at the wrong interval, due to misinterpretation of the prescription. Another error is failure to take the drug for the complete time period, such as the full ten days, for which it was prescribed.

Similar studies in Nigeria and Kenya have also yielded a 50% compliance rate. However, a recent study in Tanzania (Materia, 1977) found only 20% compliance in both rural and urban areas.

Such low rates of compliance do not inspire confidence in the ability of a pharmaceutical supply system to improve health status, unless specific steps are taken to improve these rates. Appropriate drug use can never be assumed. But it is possible to identify a constellation of factors that profoundly affect compliance, and the prescriber should take these into consideration. These factors include the illness itself, the patient, the prescriber, the medication, the types of services available, and cultural patterns towards drugs.

a. Illness

Patients with chronic illness are most prone to noncompliance. This is especially true with those illnesses that require that medications be taken for long periods of time for suppression or prophylaxis, during which time the patient has few if any symptoms (e.g., malaria, tuberculosis, rheumatic fever, etc.). Compliance is also low if drugs are being taken for mild conditions (e.g., iron for anemia or pre-natal vitamins) or if the effects of discontinuing the drug are not readily apparent (e.g., high blood pressure). In acute illnesses, such as pneumonia, patients are conscientious about medications early in the disease, but when they begin to feel better, compliance often decreases, even though the infection may not yet be eradicated.

ASSESSMENT GUIDE V.C.

Encouraging Appropriate Use by Patients

- What are the factors in your culture (country region, program) that affect patient compliance, or the degree to which patients take drugs as prescribed?
- What is the prescriber's role in patient education to improve compliance? The dispenser's role? How can these roles be expanded?
- What type of packaging and labeling can be used to encourage appropriate drug use? What type of written and/or symbolic instructions should be given to patients?
- What types of community education programs will positively influence public attitudes towards health services and the appropriate use of drugs? What is the most advantageous use of mass media, institutional programs, and personal contact?
- What are the perceived needs of the target population that can be assisted through community education?
- What are the prevalent attitudes that will have a positive or negative effect on the use of health services and drugs?
- What are the resources available for community education programs?

b. Patient

Noncompliance is more frequent at the extremes of age, in those who live alone with no family supports, in the lower socioeconomic classes, in people with less education, and in those situations where a cultural or language barrier exists between prescriber and patient. A frequent cause of noncompliance in developing countries, where drugs are sold at market prices, is the inability of the patient to buy the full course of drugs needed for therapy. Patient satisfaction with services increases compliance; likewise, patient dissatisfaction decreases compliance.

c. Prescriber

The general attitudes of the prescriber profoundly influence compliance. Is he warm or cold, supportive or condescending, positive or negative? Does the prescriber believe the therapy will work, or does he give the opposite impression? Is an effective communication pattern established with the patient or do cultural factors, language barriers, or lack of time inhibit communication? Is the prescriber more interested in getting paid for services than in treating the patient? (This last situation is a common problem where doctors may work

in government health services part of the day, and in a private practice the rest. Usually, compliance rates are much higher in the private patient than in the public patient, even where all other factors like age, socioeconomic status, and education are constant.)

d. Medication

Multiple medications and frequent dosages lead to noncompliance. Noncompliance rates among patients taking three drugs are twice as high as among those taking only one; those patients required to take a drug four times a day, likewise, have twice the noncompliance rate as those required to take it twice a day. Many drugs have similar appearances; requiring patients to take three different drugs, all of which may be white tablets, for example, creates a situation, which, for many patients, is hopelessly confusing.

With extensive marketing of attractively packaged drugs, patients everywhere, even in remote rural areas, have come to equate packaging with quality. Thus, noncompliance may be higher in government programs that dispense pills wrapped in newspaper or old envelopes. Because of poor packaging, many drugs will decompose or become contaminated with dirt, further reducing compliance.

Strong or unexpected side-effects will also lead to noncompliance. They may be real, as in the impotence associated with some blood pressure medicines, or imagined. Many people associate events in temporal sequence. One large village refused to participate in an immunization campaign because a woman in that village claimed a previous vaccination had made her sterile; in fact, she had received a tetanus immunization during a campaign to control neonatal tetanus, at the same time that she was going through menopause! This "side-effect" severely hampered village compliance with the next immunization campaign.

e. Structure of Services

Compliance increases where patient followup is provided through outreach services, or if a provider can visit occasionally in the home to supervise medications. Likewise, if patients are able to make return visits to a provider, if problems develop or to ask questions, compliance rises.

f. Culture

Everyone who has provided health services is quite familiar with the cultural restraints that inhibit compliance. For example, many Latin Americans believe in a "hot-cold" theory of disease: a "cold" disease is treated with "hot" drugs or food, and "hot" diseases are treated with "cold" drugs. Such classification of diseases, foods, and drugs has been passed on through the generations, and new drugs are constantly added. Both diarrhea and penicillin are classified as "hot". Thus, a patient who believes in this theory will not take ampicillin prescribed for bacillary dysentery, unless the potential problem has been well understood; an alternative antibiotic may have to be prescribed.

A major problem with the use of oral rehydration salts is the unavailability of standard one liter containers in rural areas, which results in over-

or under-dosage of the sodium and potassium salts. In some countries where water is scarce, patients have been known to eat the oral salts in dry form, thus aggravating the condition they were intended to treat.

* * *

In summary, compliance is highest when the drug is prescribed by a familiar, sympathetic, well-liked provider who believes in the medication and adopts a positive reassuring manner. Compliance increases if the number of drugs is few, dosages are limited, side effects are minimal, a proper explanation is given, written instructions exist, and the prescription fits into the patient's lifestyle and cultural pattern. Figure V.C.1. illustrates these factors.

The following sections will suggest some strategies for improving compliance.

2. PRESCRIBER'S ROLE IN PATIENT EDUCATION

The most common reason for patients to fail to take their drugs appropriately is inadequate explanation by the prescriber. Prescriber means any provider of services which include medications, whether it is a doctor, nurse, student, health auxiliary, shopkeeper, pharmacist, or community health worker. Studies in the United States have shown that medical students have better compliance rates than graduate doctors, and nurses even better than medical students. The common factor for successful compliance is the time spent communicating with the patient. Practicing physicians all too often are forced to rush through their patient encounters and terminate them by providing a prescription. Students and nurses generally have more time available for explanation. Thus, in situations where the physician is overworked and does not have time for adequate explanation, a team approach can be adopted whereby the physician makes the diagnosis and prescribes, and another member of the health care team does the explanation.

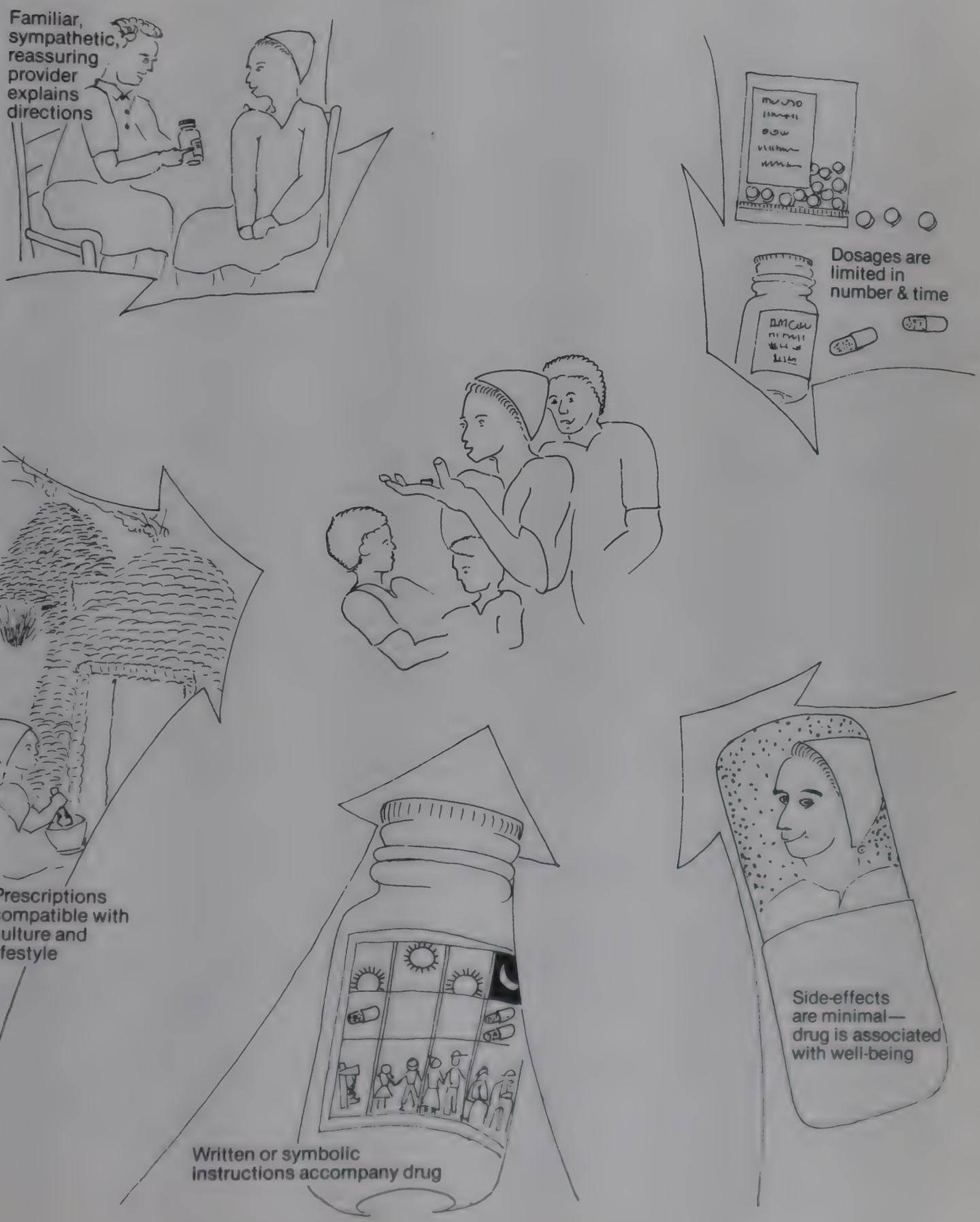
Three factors should be included in every patient education effort:

(1) The nature and prognosis of the illness -- Studies have correlated control of hypertension (high blood pressure) with simply knowing what "hypertension" means. A basic principle is that a patient with adequate knowledge of his illness actively participates in his own care and will tend to comply better with his therapy than an uninformed patient.

(2) The good and bad effects of the medication -- The name of the medication why it is used, and what effects it will have should all be explained to the patient. It is important to stress the beneficial effects as well as any potential side effects. The patient must understand that potent medicines may have both positive and negative effects. Focusing only on the side effects will create a negative atmosphere that does not support continued drug compliance. However, not mentioning the possibility of adverse reactions may mean the patient will stop his

Figure V. C. 1.

Factors Influencing Patient Compliance


Familiar, sympathetic, reassuring provider explains directions
Dosages are limited in number & time
Prescriptions compatible with culture and lifestyle
Written or symbolic instructions accompany drug
Side-effects are minimal—drug is associated with well-being

drug at the first signs of any unexpected effect. A proper balance must be struck.

(3) Fitting the drug therapy into the patient's lifestyle -- Hundreds of years ago Hippocrates, the father of medicine, wrote that in order to treat an illness the doctor must know the person, his job, his town, and the way he lives. This is still true today. To tell a patient that he should take his pills three times a day with meals when he actually eats only two meals a day will cause confusion and increase the chances of treatment failure. To prescribe tetracycline to an individual whose diet is principally milk and cheese will prevent adequate absorption of the drug due to calcium precipitation of the tetracycline salt. Women sometimes refrain from taking drugs during their menses, no matter how urgently they need the drug.

Each of these factors must be explored and understood in order to maximize patient compliance. Figure V.C.2. illustrates the communication between the prescriber and the patient, and the factors that influence it. The prescriber must recognize standards established by the health system in which he or she functions. This health system exists within a particular sub-culture that values health and education, and is usually formed of people from the middle and upper classes. The patient responds not only to his/her own needs, but to those of the family, and the sub-culture in which they exist. This sub-culture is often from a different educational and socio-economic background than the prescriber's and may have a different religion or language. In the midst of all these potential barriers, two levels of communication are being attempted: technical communication that explains the disease and the medication, and personal communication that describes the patient, his lifestyle, and the effects the disease and its treatment may have on them. All of this occurs within the dominant culture of the country or region in which both prescriber and patient live. Small wonder that this process breaks down so frequently, and treatment failure rates are so high.

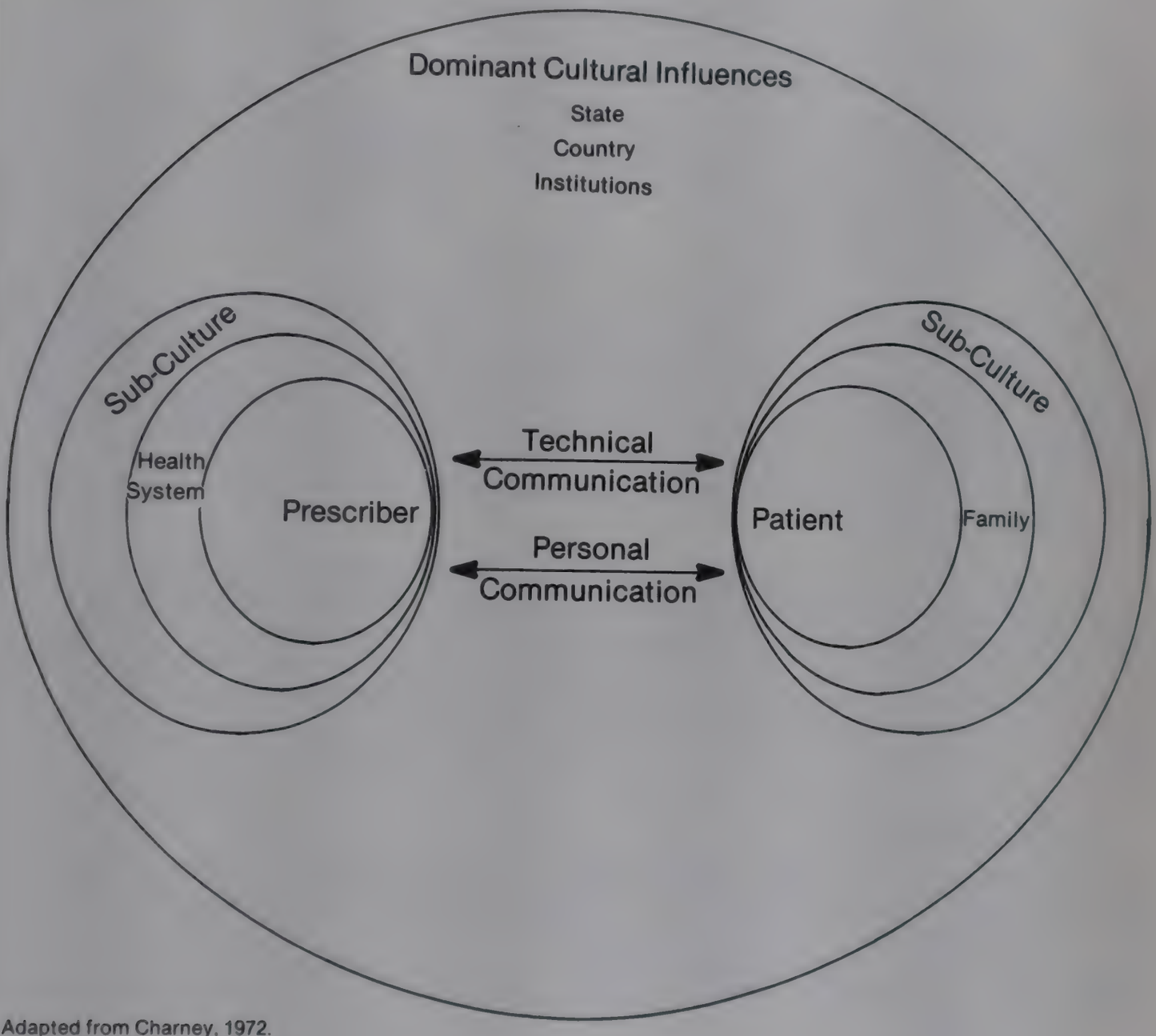
The job of the prescriber is facilitated when trained dispensers are available to provide additional patient education.

3. DISPENSER'S ROLE IN PATIENT EDUCATION

Given the multiple factors that influence patient education and the amount of time required to do it effectively, a team approach to therapy can be an effective strategy when there is sufficient staff available. It is then useful to have someone dispense the drugs who is different than the prescriber. This approach works best in outpatient or clinic settings where there is a physician, a nurse, and other health personnel available (e.g. a pharmacist or technician). Obviously, the further towards the periphery of a rural health system, the more difficult this strategy becomes; at the health post and community levels the prescriber and dispenser is the same person! Fortunately, the patient demand on nurse auxiliaries or community health workers is often not so overwhelming that they do not have time to educate the patient. In fact, this usually is the primary function of these categories of health

Figure V.C.2.

Prescriber-Patient Communication



Adapted from Charney, 1972.

workers, and the drug therapy is used as the initial focus for a wider array of educational activities.

In situations where the prescriber and dispenser are separate, clearly defined roles should be established. The prescriber makes the diagnosis and prescribes appropriate treatment. Therefore, the prescriber should have the responsibility to explain the illness and its prognosis to the patient. This need not take long, but it does require an interest on the part of the prescriber.

The dispenser should know the mode of action of the drugs used and their potential good and bad effects. He should also understand all the factors that influence drug activity, and how they relate to patient lifestyle. The

dispenser should have an area, away from other waiting patients, so that communication can be more confidential. It need not be a separate room; a screen around a dispenser's window can be sufficient if space is limited. The dispenser should also have a checklist for each type of drug he gives out, in order to understand the patient's habits, diet, etc., and how they will influence drug effectiveness. This does not need to take a long period of time. What is important is a standard procedure that is followed for each drug dispensed, and support and supervision from other members of the health team, including the prescriber. If an environment is created that conveys that patient education, and the dispenser's role in it, is vitally important, then this activity will work well to improve patient compliance.

4. PACKAGING AND LABELING

The appearance of a drug can have an important influence on the patient's attitude toward the medicine and, therefore, his compliance. Dispensing drugs in clearly labeled course-of-therapy packaging (discussed in Chapter V.B.) is one way of improving both compliance and dispensing efficiency. The attractiveness and cleanliness of prepackaged medications increases patients' confidence in the drugs. In addition, course-of-therapy packets usually contain standard labels which further increase the likelihood that the medicine will be taken correctly.

Even when drugs are dispensed from bulk containers, they should be clearly labeled with the drug name and instructions for use. Experience in some countries indicates that, even where illiteracy rates are high, patients can usually find someone in their household or village who can read instructions written in the local language. Nevertheless, for patients who cannot read, symbolic labels have been found to be most effective.

Symbolic Labeling

Several models have been implemented successfully (Figure V.C.3). One model indicates correct dosages and dosage intervals by the movement of the sun. In cultures where clocks are known, the face of a clock can be used with hands drawn in to point to the time each pill should be taken. For example, this illustration shows that one pill should be taken at 6 a.m., and 2 pills at 9 p.m.

Each culture may use different symbols. The important principle is to test each proposed symbol with a sample of patients before adopting it for an entire program. Symbolic labels should appear with written instructions, rather than replace them.

5. COMMUNITY EDUCATION ACTIVITIES

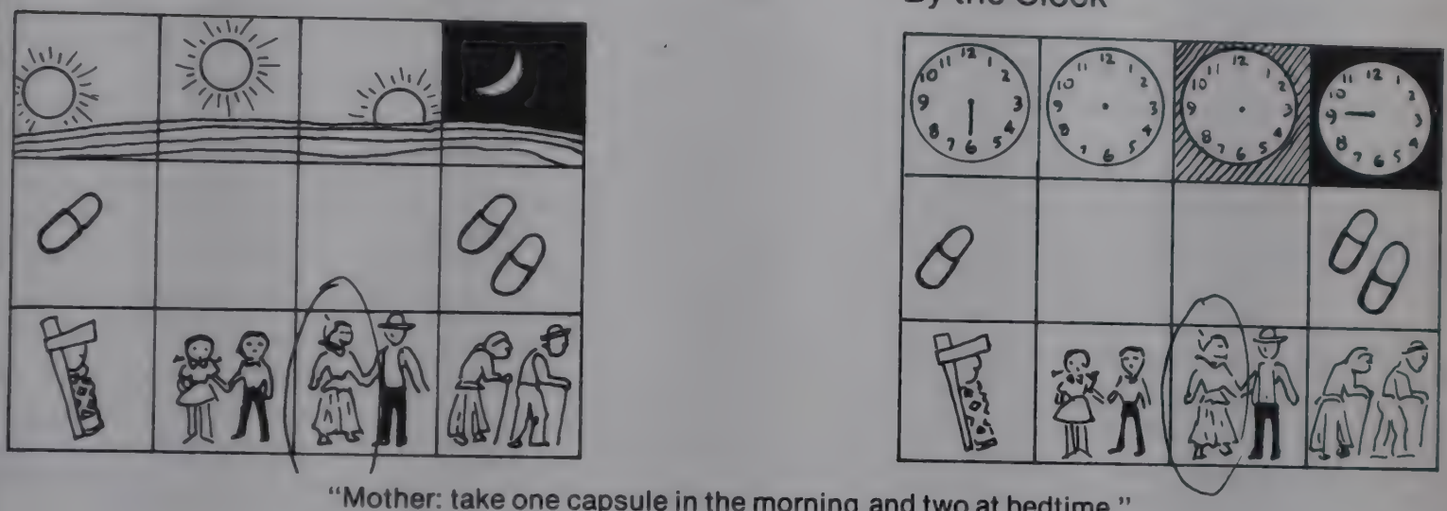
Community education, in the context of this manual, has the primary objective of influencing public attitudes toward:

Figure V.C.3.

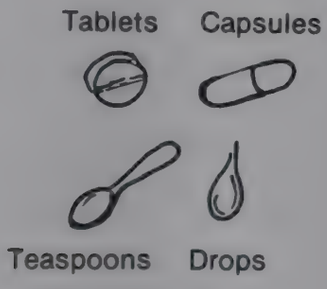
Examples of Symbolic Labeling

TO ENCOURAGE CORRECT DOSAGE AND INTERVAL:

By the Sun *or* By the Clock

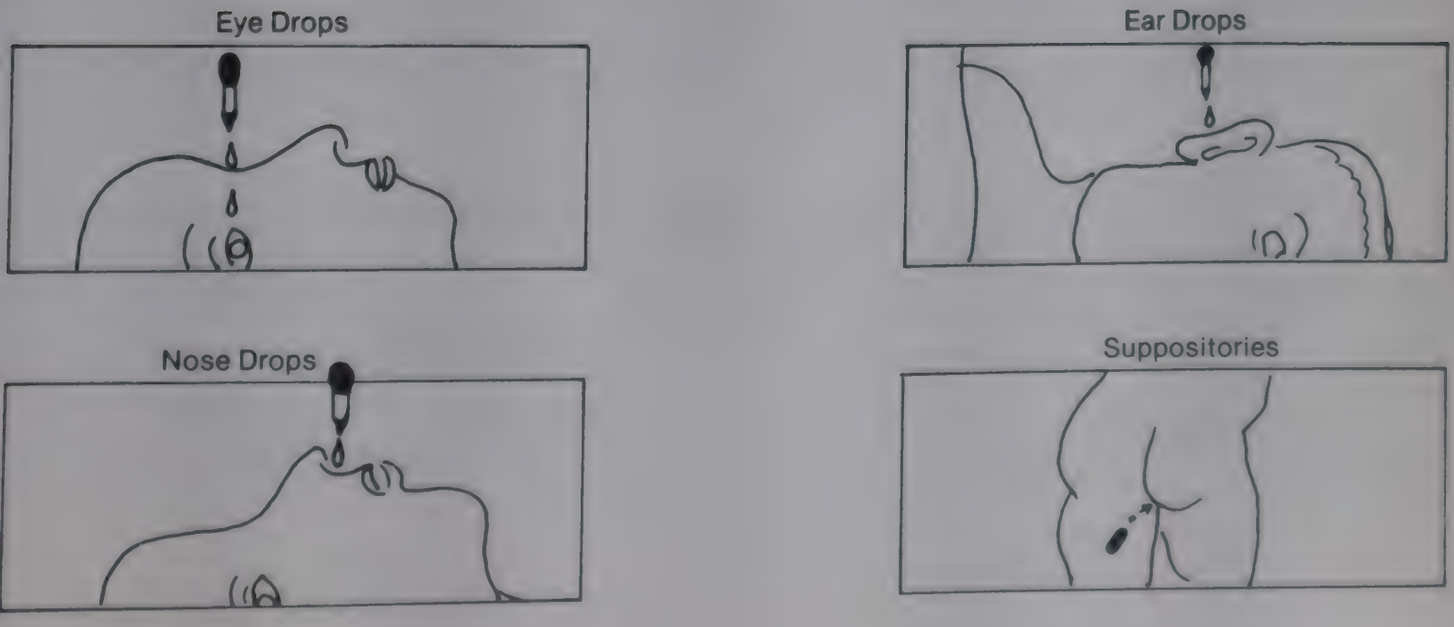


"Mother: take one capsule in the morning and two at bedtime."



Stamps or drawings the dispenser can use to indicate number of tablets, capsules, teaspoons, or drops to be taken.

TO ASSURE CORRECT ROUTE OF ADMINISTRATION:*



*Adapted from Morley, 1973

- a positive perception of health services and their ability to meet the needs of the people, and
- the appropriate use of health services and available drugs.

A variety of methods can be used in community education programs:

a. Mass Media

These may involve spot radio announcements and short educational programs; newspaper articles and advertisements; movie or television shorts (where available); printed circulars or posters. The involvement of public communication channels provides access to the widest number of people, but it is also the most expensive method. Even if "air time" is donated, a professional is usually required to design the educational announcements.

Mass media campaigns work best for general orientation of the target population to the use of health services, or for special campaigns such as immunizations or oral rehydration. Studies are underway in several countries to evaluate the effectiveness of mass media educational programs on the preparation and use of oral rehydration in the home and their impact on infant mortality and morbidity from diarrheal disease. Another interesting use of mass media is to provide short continuing education programs to community and auxiliary health personnel.

b. Institutional Education Efforts

This method uses the resources and facilities of the health service institutions (hospitals, health centers, dispensaries) to educate small groups of people or individuals about specific health problems, or specific programs that involve drug therapy. These often take the form of slide presentations or poster sessions with small groups of people, either at the facility or within the community. This education method tends to be relatively inexpensive, since the trainers can be auxiliary or experienced community health personnel, and many of the educational materials can be made locally. Family planning programs have successfully used this approach to motivate women to be contraceptive acceptors, but the technique can be equally successful in any other health program that has a large target population. It does not work well for narrowly defined audiences or to educate about special patient needs (e.g., for diabetics).

As mentioned earlier, attractive packaging of drugs and written instructions can considerably improve institutional efforts at community education. Some programs have developed distinctive colors, or a logo, which is prominently displayed at all health facilities that dispense government drugs. With appropriate educational programs, people will recognize the logo or distinctive colors, and demand for the services that use these drugs will increase. This approach likewise has worked well in family planning programs, but has also been successfully applied in national basic medicine programs.

c. Personal Contact

This technique works well when a more individualized approach is required. Prescriber and dispenser explanations to individual patients fall into this category. However, it is most effective within the community setting, such as when a representative of the health services talks with community leaders to better understand community needs or to gain their support for health programs. The leaders can, in turn, educate the community members, and this is the basis of many community health projects.

Home visits by health personnel are another effective use of personal contact, and studies have shown that they dramatically increase drug compliance rates, especially for chronic diseases such as tuberculosis or Hansen's disease. Some program evaluations have shown that home visits alone, independent of any drugs dispensed, can improve morbidity or mortality rates. Personal contact appears to have a general protective effect in maintaining a positive state of health.

It is impossible to state whether one method is better than any other. In actual practice, a combination of techniques is usually needed, and the effective health worker will be skilled in all of them. Regardless of the techniques used in a community education program, some basic principles should be followed. These are:

- Identify the perceived needs and desires of the people to be served;
- Identify the attitudes (fears, misunderstanding, biases) which may have an adverse effect on the program, and those which may have a positive effect;
- Identify the resources available for community education (human, material, financial);
- Design specific educational programs to meet the perceived needs of the people, that reinforce positive attitudes towards health and minimize negative, and can be implemented within the limits of the resources available. When needed, make appropriate use of consultants or experts in community education.

SUMMARY

An efficient logistics system has little impact if patients do not take proper drugs in appropriate dosages at the correct dosage intervals. Patient compliance may be affected by the following factors:

(1) Illness -- compliance lower for chronic illnesses, for long-term drug regimens, when patients have few symptoms;
(2) Patient -- compliance lower at the extremes of age, when patients have no family supports, among lower socioeconomic classes, among

the less educated, when cultural or language barrier exists, when patients are dissatisfied with services;

(3) Prescriber -- compliance lower when prescriber is condescending, negative, pessimistic about the therapy; when cultural or language barrier exists;

(4) Medication -- compliance lower with multiple medications and frequent dosages; poor packaging; real or imagined side effects;

(5) Structure of services -- compliance lower where patient follow-up difficult or impossible, where health services not easily accessible;

(6) Culture -- compliance lower where beliefs or lifestyle interfere with prescribed drugs or dosages.

The most common reason for patient non-compliance is inadequate explanation by the prescriber. If sufficient staff is available, prescriber and dispenser should be different. The dispenser, then, spends more time in patient education. Every patient education effort should include:

- nature and prognosis of the illness,
- potential positive and negative effects of the medication,
- consideration of patient's lifestyle.

The dispenser should have a separate area to allow for private communication, and should follow a standard procedure.

Attractive and clean packaging and clear labeling increase patient compliance. Symbolic labels have been implemented successfully when adapted to the local culture.

Community education activities may include the use of mass media, institutional education efforts, and personal contact. The effective health worker will follow these basic principles:

- Identify the perceived needs of the population.
- Identify the attitudes which may affect the health program.
- Identify the resources available for community education.
- Design educational programs accordingly.

CHAPTER V.C. REFERENCES

Blackwell, B.: The Drug Defaulter. Clin. Pharmacol. Ther., 1972.

Blackwell, B.: Drug Therapy: Patient Compliance. New England Journal of Medicine, 289: No. 5, 249-252, 1973.

Charney. E.: Patient-Doctor Communication: Implications for the Clinician. Journal of Pediatrics Clinics of North America, Vol. 19, No. 2, 263-279, 1972.

Francis, V. et al: Gaps in Doctor-Patient Communications: Patient's Response to Medical Advice. New England Journal of Medicine, Vol. 280, No. 10, 535-40.

Harwood, A.: The Hot-Cold Theory of Disease: Implications for Treating Puerto Rican Patients. Journal of the American Medical Association, pp. 1153-58, May 17, 1971.

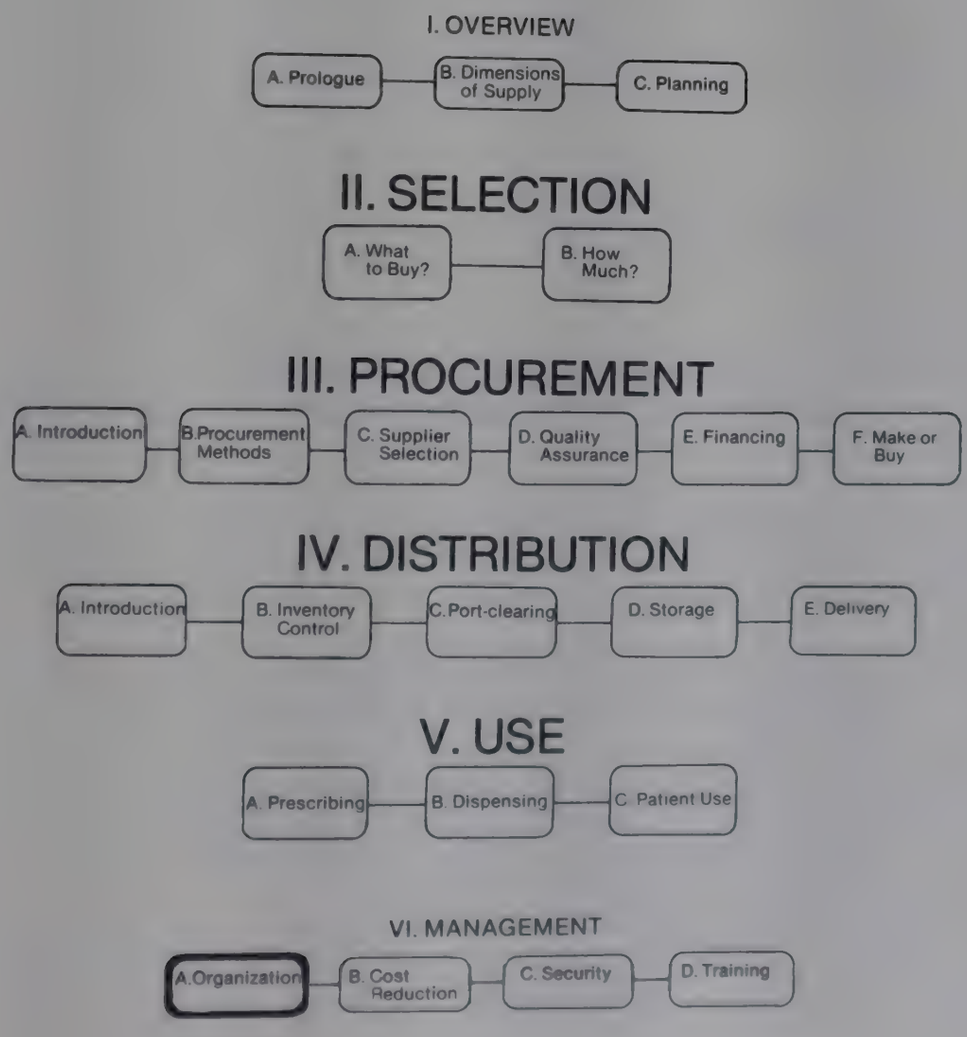
Materia, M.L.B.: Patient Drug Compliance in a Rural and an Urban Environment in Tanzania. Dar Es Salaam, Tanzania: Division of Pharmacy, Faculty of Medicine, University of Dar Es Salaam, 1977.

Mazullo, J.M. and Lasagua, L.: Take Thou ... But Is Your Patient Really Taking What You Prescribed? Drug Therapy, pp. 11-15, November 1972.

Morley, D.C.: Pharmaceuticals in West Africa. London: University of London Institute of Child Health, undated.

Chapter VI.A.

Organizing Drug Supply



	Page
1. ORGANIZATIONAL STRUCTURE AND ADMINISTRATION	464
a. Level of Organization	465
b. Organizational Structure	465
Centralized Model	
Directorate Model	
Decentralized Model	
c. Role of Committees	471
2. INFORMATION SYSTEM	471
a. Functions of the Information System	471
b. Basic Considerations in Designing the Information System	472
Base the Design on Information Needs at Each Level	
Keep the System Simple	
Allow the Information System to Grow over Time	
c. A Comprehensive Information System for Public Drug Supply	473
d. Performance Monitoring	473
3. PERSONNEL	474
a. Staffing a Pharmaceutical Supply System	478
b. Manpower Planning and Development	481
c. Importance of Routine Supervision	482
4. FACILITIES, EQUIPMENT, AND SUPPLIES	483
5. FINANCIAL MANAGEMENT	485
a. Development versus Operating Budgets	486
b. Procurement Cycles and Fiscal Cycles	486
c. "Free" Drugs	486
d. Accountability to Donor Agencies	487
e. Foreign Exchange Limitations	487
f. Over-Requisitioning by Health Facilities	487
g. Cash Flow in Drug Sales Programs	488
h. Staff Salary Levels	488
SUMMARY	489
REFERENCES	490

Organizing Drug Supply

The preceding chapters point out that pharmaceutical supply requires the management of a large number of complex activities. This chapter presents an overview of some of the management concepts which are most relevant to pharmaceutical logistics. Assessment Guide VI.A. introduces some of the issues which are important here.

Since no two programs are alike in their needs or in the type of problems encountered, it is safe to say that there is no single organizational framework that will fit all situations. The process of organizing the supply system will involve interactions among multiple divisions within the Ministry of Health, and between other ministries and the MOH. For these reasons, no two logistics organizations will look the same, but some general principles that apply to all of them are summarized below:

- The senior officials responsible for drug supply should have sufficient status to assure that supply problems receive prompt attention and strong support. The greater the responsibility and prestige associated with supply activities, the higher the calibre of staff which will be attracted.

- The closer the supply system leadership is to top government officials, the greater will be the potential for linkages and communication with other government activities.

- The responsibility for each supply function should be clearly defined and assigned to a specific individual. A summary of assigned responsibilities should be written in the form of a manual or organization handbook.

- Assignment of responsibility should always be coupled with sufficient authority to implement the procedures and to assure proper performance of assigned tasks.

- Channels of communication should be clear and direct among the levels in the supply system and with other areas of government.

- Relationships with commercial interests are necessary and often fruitful, but they should be clearly defined and circumscribed to prevent illicit influence.

- Sufficient resources (staff, equipment) must be assigned to each component within the organization to fulfill its assigned responsibilities. The most detailed organizational structure cannot function without resources.

ASSESSMENT GUIDE VI.A.
Drug Supply Management

- What government ministries, offices, divisions, and agencies are (will be) involved in drug supply? What are the relationships of these groups in a table of organization?
- Where are the strong and weak points in communication and cooperation among these groups?
- Is the current administrative structure (table of organization) operating effectively? Is the structure suited to the characteristics and needs of the individual country?
- How does the existing or proposed organizational structure influence the image and prestige of supply management? The cost of the supply system? The use and specialization of available staff? The ease and speed of communication? The utilization of drugs?
- List all of the individuals who have (will have) responsibility for any aspect of drug supply. What are the qualifications of these individuals? What are their detailed job descriptions? Are these job descriptions written?
- What plans have been made for supply management manpower requirements? For recruiting and training adequate numbers of competent personnel in each of the areas of drug supply?
- What systems exist for recording and reporting information about drug prices, inventories, and consumption? Are these systems reliable? Do they supply all the information necessary for informed management decisions?
- Are storage and transportation facilities adequate? Are they efficiently utilized? How are they controlled and by whom?
- How are pharmaceutical supplies funded? Who manages these funds and how are they managed? What special financing problems exist in the area of pharmaceutical supplies?

1. ORGANIZATIONAL STRUCTURE AND ADMINISTRATION

One of the fundamentals of supply management mentioned above is the clear assignment of responsibilities and establishment of authority relationships. Chapter I.C. discusses the importance of diagramming the table of organization; in this section, further consideration is given to some of the important characteristics which determine the organizational structure.

a. Level of Organization

Pharmaceutical services can be organized at the local, district, regional (state, provincial), or national level -- often at the same level of government at which health services are administered. Although health planners and advisors interested in pharmaceutical supply cannot generally determine the level of government at which the services will be coordinated, it is important to clearly establish at the outset which levels of government have authority for drug supply.

b. Organizational Structure

Although no single type of organizational structure will suit all programs, the commonly observed alternatives have distinct advantages and disadvantages which should be borne in mind when dealing with an existing system or designing a new one. The organizational structure of pharmaceutical supply programs is typically one of three types:

- CENTRALIZED, in which drug supply is managed by a separate pharmacy or logistics unit;
- DIRECTORATE, in which a separate logistics unit coordinates logistics activities, while the responsibility for performing logistics functions remains decentralized;
- DECENTRALIZED, in which each government program, each agency, and sometimes each facility is responsible for its own selection, procurement, storage, and use of drugs.

These models are compared in Figure VI.A.1.in terms of the characteristics described briefly below:

- Potential for economies of scale -- Centralized purchasing aids in obtaining bulk rates. In addition, centralization of operations may reduce operating costs, although a larger initial capital investment is often required for central warehouse facilities, vehicles, and other facilities and equipment.
- Staff utilization and specialization -- Decentralized organizations are forced to spread out the limited number of qualified staff members and they each perform multiple functions. Staff specialization is easier in centralized organizations.
- Communication and coordination -- Decision-making and coordination is generally more rapid and less prone to confusion in smaller, decentralized organizations.
- Image and prestige of supply management -- Centralized programs and programs in which there is a directorate of supplies management ostensibly grant more significance to supply activities.

Figure VI.A.1.

Comparison of Organizational Models for Logistics Management

Model	Economies of Scale	Staff Utilization	Communication and Coordination	Image and Prestige of Supply Management	Drug Utilization Patterns	Observations
Centralized Model	• Potentially large (bulk purchasing, inventory consolidation, vehicle maintenance) • Large initial capital investment possible for facilities, equipment	• Promotes staff specialization • Uses limited numbers of professionals efficiently	• Prone to communications breakdowns • Coordination difficult • Decision-making remote from user • Responds slowly to requests	• High visibility and prestige	• Standard and rational therapeutic guidelines possible	• Most effective in small to medium programs; complete centralization difficult in large country • Dependable systems of communication and transportation are prerequisites • Good structure for development of new programs
Directorate Model	• Some economies (esp. bulk purchasing) • Large capital investment (central store, vehicles) not necessary	• Allows specialization in centrally managed areas	• Some communication breakdowns • May respond slowly to special requests	• Supply management recognized as important	• Some standardization possible	• Useful transition model from decentralized to centralized • Reliable systems of communication are needed • Reasonable alternative where individual programs, areas, or facilities resist centralization
Decentralized Model	• Few (much duplication of facilities) • Low capital investment • High operating costs due to duplicate staff functions	• Little specialization possible • Qualified staff diffused and inefficiently used	• Rapid, flexible communication and coordination • Planning and decision-making close to user	• Low visibility, low importance	• Unlikely to rationalize or improve therapy • Existing inefficiencies readily perpetuated	• Most effective in large, geographically-diverse country • Useful where there are many individual programs or geographic units, each with strong, effective management • Each independent program, area, or facility must have ready access to reliable, economical supply sources; best in countries with well-developed, competitive local suppliers

- Effect on drug utilization patterns -- Centralization of procurement activities requires centralized drug selection and this opens the possibility for greater use of professional committees and specialist consultants in drug selection. Drug utilization patterns are thus less prone to influence by local, idiosyncratic, or irrational practices.

With these characteristics in mind, each of the three models can be considered in greater detail. Although these models are not the only organizational structures which exist in supply programs, they are the most common schemes. An understanding of the advantages and disadvantages of each model should help in designing new programs or improving existing programs.

Centralized Model -- In this model, drug supply is managed under a separate pharmacy or logistics unit. The authority and responsibility for selection, procurement, distribution, and use of pharmaceuticals is coordinated through this unit. Although there may be innumerable individual health facilities and specialized programs, they are all dependent upon the central supply division. Obviously, not all functions can be centralized. At the very least, storage and dispensing must occur at individual locations. Nevertheless, the responsibility for overseeing these activities remains at the central level.

The major advantages of the Centralized Model are that it facilitates the development of staff specialization and that it can achieve economies of scale arising from quantity discounts, more efficient storage of large quantities, better use of transportation, and similar savings. The major drawbacks to the Centralized Model are that it tends to respond slowly to new or special needs of the user organizations and it is prone to breakdowns in communication. Country Study VI.A.1. describes the Centralized Model operating in Malaysia.

Centralized Models are most effective for small and medium sized jurisdictions. If a program covers a large geographic area, then good communication and transportation routes must be available between the central coordinating agency and the user organizations. Because this model makes the most efficient use of limited staff expertise and can achieve the greatest long-term savings, it is probably the best model to institute in programs which are entirely new.

Directorate Model -- In some settings it has proven advantageous to establish a division of logistics to coordinate activities, while maintaining decentralization of most of the functions necessary for drug supply. In this "Mixed Model", some functions are centralized, while others are decentralized. Frequently the logistics division is responsible for arranging procurement and bulk delivery; the individual user organizations are then responsible for further distribution and control of drug use. The logistics division may play an important role in organizing an effective drug selection process, or it may simply procure the items requested by user organizations.

The Directorate Model has the advantages of promoting the development of staff specialization -- particularly in procurement -- and of achieving some economic savings. Such a model may or may not reduce communication breakdowns and coordination problems, since there may be conflict between the authority and expectations of the central logistics unit and the user organizations. Peru provides one example of a Directorate Model (Country Study VI.A.2.).

Country Study VI.A.1.

Organization of Pharmaceutical Supply in Malaysia

Health services in Malaysia are a federal responsibility, and the pharmaceutical services and supply system makes up one division of the Ministry of Health. This Pharmacy Division has centralized control of all aspects of public drug supply. The Division's leadership has long promoted professional standards of pharmacy, constantly improving the system of production and supply, and, most recently, involving hospital pharmacists in establishing information services to encourage rational drug use. The major physical plant operated by the Pharmacy Division is the State Pharmaceutical Laboratories and Stores (SPLS), with four major divisions: the Pharmaceutical Manufacturing Unit, the Government Medical Stores (GMS), the School of Dispensing, and the Analytical Control Unit (quality control laboratory).

The Government Medical Stores (GMS) -- Central government purchasing of medical supplies has existed for many decades. The current GMS was opened in 1964 in a warehouse adjacent to the country's production facilities. It employs about 140 people to handle purchasing, port clearance, warehousing, inventory control, and dispatching. The staff is headed by a pharmacist, and 3 other pharmacists assist with administrative and supervisory functions. Storekeepers are civil service employees and most have been trained at the GMS in its medical storekeeping course.

Selection -- The current process of drug selection has evolved over time since the GMS has been in operation. There is no national formulary committee which reviews the list of selections. Instead, additions and deletions are made generally on the basis of demand. Government hospitals and health services are usually limited to those drugs offered by the GMS. When they wish to purchase drugs not currently available, State Pharmacists must request a Clearance Certificate, which allows them to buy directly.

Procurement -- A continuous inventory for nearly 7,000 items is maintained on kardexes, which are updated daily with the issuing and receiving forms. A system of scheduled indenting is used whereby the kardex for a different category of drugs is reviewed each month, and a list of items and quantities for purchase prepared. For the most essential drugs and selected other drugs, estimates of annual consumption are requested from the states to supplement the consumption information available from the kardexes.

Government Production -- Pharmaceutical production has had a long history in Malaysia. The current facilities were opened in 1964 to replace the 18 scattered facilities which existed at that time. The production unit is equipped with modern manufacturing machinery for the production of injectables, tablets, and galenicals. The net savings from government production, believed to be substantial, are attributed to plant efficiency, to low domestic wages, absence of import taxes on raw materials, greatly simplified packaging, and the absence of payments for research, marketing, and return to investors. The plant is headed by a well-trained, experienced pharmacist and each of the production divisions is headed by a pharmacist specialized in industrial pharmacy. The plant operates its own training course for pharmaceutical production laboratory assistants.

Distribution -- Quarterly indents are received by the GMS from the 13 State Medical Stores. The GMS then prepares a quarterly pick-up schedule which requires that states collect their own supplies every one to two weeks. Bulk items go by railroad, which is slower, but cheaper. Shipments to East Malaysia go by sea. From the State Medical Stores, goods are distributed to the consuming units on a weekly, monthly, or quarterly basis, depending on consumption. A typical state may have one general hospital, 2-4 district hospitals, 4-5 maternal and child health clinics, and 20 or more health centers, each of which it supplies directly with its own transport. Other facilities may be supplied in turn by the hospitals and health centers. Most health facilities are within one day's drive of the State Medical Store. Good telephone communication allows emergency drug requirements to be rapidly filled.

Although government drugs are distributed free to patients, each state has a drug budget and drugs supplied to the states by the GMS are charged against that budget. In practice, state allocations for drugs are kept in the Ministry of Health treasury and simply transferred to the GMS fund when drugs are issued.

Administration and Supervision -- The Director and Deputy Director of the Pharmacy Division attempt to make regular visits to the State Medical Stores to meet with State Pharmacists and to review at first hand the performance of the supply system. Each State Pharmacist, while under the professional supervision of the national Director of the Pharmacy Division, is administratively responsible to the State Medical and Health Services Director. As the person responsible for virtually all aspects of pharmaceutical services within the state, his responsibilities include the selection of drugs for State Medical Services (from the GMS list), overseeing the State Medical Stores, supervising government pharmacists and dispensers, enforcing drug and pharmacy control laws, and participation in national planning.

Comment -- The Pharmacy Division of this large centralized health system seems to be quite successful. Contributing to this success are many factors, including the availability of skilled and experienced pharmacists, administrators, and other personnel for leadership positions; the existence of a good communication system and reliable supply information system; the supply of adequate financial and material resources; and the opportunity for the administrative structure to develop gradually over many years as the health programs have expanded.

Country Study VI.A.2.

Organization of Pharmaceutical Supply in Peru

Peru's Basic Medicine Program (BMP), established in 1971, forms a division of the Pharmaceutical Department of the Ministry of Health. It serves essentially a coordinating function in the drug supply system, involved directly in selection and procurement, and overseeing many distribution activities.

The primary responsibilities of the BMP are to (1) issue a periodic (usually bi-annual) Official Requisition for Basic Medicines and call for bids on the Requisition, (2) review and award contracts on the basis of offers received, (3) direct the quarterly and supplemental monthly deliveries of Basic Medicines by the pharmaceutical firms to the Users, (4) make payments for the Basic Medicines used by the Ministry of Health Programs, and (5) assure the routine quality control testing of the Basic Medicines.

The Ministry of Health's 57 area hospitals and the Employee's Social Security Program are required to use drugs provided through the BMP. In addition, there are 13 other Ministry of Health hospitals, other public Users, and 11 cooperatives comprising the list of 94 current Users.

Selection -- A full-time staff operates the BMP on a daily basis; in addition, there are several committees with specific responsibilities during the periodic tendering process. The first of these committees, the Commission for the Study of the Official Requisition for Basic Medicines, is responsible for the creation and revision of the "National Formulary" which is the basis for purchasing. Its members include representatives from various public programs and academic institutions.

Purchasing -- Purchasing is done in a single bid every two years. Although reliable consumption data do not exist, the Review Commission collects from Users suggestions for additions to or deletions from the Official Requisition. A modified Official Requisition is then circulated, and Users, in turn, report estimates of their two-year needs. These estimates are collated by the BMP staff, and public distribution of the "Chart of Needs" constitutes the official call for bids. The bid specifications require that most drugs be provided in standard blister packs, boxed and labeled with the Program's name.

The Technical Committee, consisting of representatives from the Health Departments of the Armed Forces and from the Ministry of Health, is responsible for recommending a specific supplier for each product. The Economic Board, chaired by the Minister of Health, reviews these recommendations and makes the final decision regarding the source of supply.

Distribution -- Distribution to the main hospital in each of the 57 Ministry of Health Hospital Areas, to the Social Security facilities, and to nearly forty other sites is the responsibility of the supplier. The Basic Medicine Program provides suppliers with delivery timetables, but the BMP maintains no warehouses, vehicles, or delivery services of its own. The suppliers must check the quality, quantity, and intactness of deliveries, and bear all risks and expenses until the goods are received at the User locations. Further distribution is the responsibility of the Users.

Distribution Within Hospital Areas -- The 57 Hospital Areas serve as the delivery point and coordinating center for a total of 159 hospitals, 343 Health Centers, and several hundred Health Posts which together constitute the Ministry of Health service facilities. Each Area Hospital maintains a central storeroom from which drugs are distributed at 1 to 4 week intervals to the health centers and health posts. A typical area hospital will serve 2-3 other hospitals, 5-7 health centers, and 5-10 health posts. Drugs are often carried by the doctor from the hospital to the health center or post; distribution to the centers and posts is generally based on their requisitions.

The health center is staffed by at least one physician and necessary support personnel, while a health post is staffed by nurse auxiliaries with occasional visits by a physician. At Health Centers, there is often a pharmacy assistant to manage the medicine storeroom. At Health Posts the responsibility falls to the nurse auxiliary as one of many tasks for which she is responsible.

Shortages occur and are handled in one of three ways: (1) Monthly requests for additional deliveries are sent to the Ministry of Health. This is often a slow process and current economic difficulties have meant that often there are no funds available. (2) Redistribution within the Ministry of Health is a common source of needed medicines, since there is maldistribution of drugs by type as well as by quantity. (3) Hospitals may be authorized to buy drugs commercially when they are out of the Basic Medicines. However, budgetary restrictions make this difficult.

Rural Supply of medicines by way of the Health Centers and Health Posts has been improved by the Basic Medicine Program. Prior to the Program, patients were dependent upon pharmacies and, where they did not exist, upon variety stores (authorized by law to sell drugs where pharmacies do not exist). One study showed that over 90% of the people can buy their medicine at Basic Medicine prices, while less than 50% are able to do so when forced to go to a commercial pharmacy.

The Directorate Model is advantageous in a setting in which the geographic or institutional separation of user agencies and facilities makes a single, centralized system unrealistic. It requires adequate storage and transportation facilities in the user organizations or the commercial sector to assure regular supply. The Directorate Model can improve the efficiency and economy of drug supply without necessitating the construction of large government storage facilities or the acquisition of vehicles.

Finally, the Model is useful as a transition structure in situations where multiple government agencies and facilities cannot immediately be brought under one supply system, but improved coordination and greater economy is nevertheless desired.

Decentralized Model -- When public health facilities first begin supplying pharmaceuticals, it is frequently in a decentralized and often haphazard manner. In the Decentralized Model, each government program, each agency, and sometimes even each facility is responsible for its own selection, procurement, delivery, storage, and use of drugs. These functions are generally performed by individuals who are also responsible for several other activities. With this type of organization decisions are generally made more quickly, special needs can more readily be met, and there is less chance for confusion or communication breakdowns, since the organization is much less complex. However, in the Decentralized Model staff members do not as readily become specialized in specific logistics functions; total operating costs tend to be higher because of less bulk purchasing and wasteful duplication of storage and transportation activities; and supplies management and logistics are not as easily identified as unique and vital activities. Under the Decentralized Model, drug supply management has no individual identity, making the monitoring of specific activities more difficult. It is also more difficult for senior officials to focus on drug supply problems which arise.

A Decentralized Model is most likely to succeed where the individual programs, agencies, or facilities are effectively managed and have adequate storage and transportation facilities. Despite its drawbacks, a Decentralized Model may be the most effective model in countries with wide geographic variations and difficult transportation and communication. It is also effective where the government itself is large and quite compartmentalized.

Program and geographical considerations are important in determining the degree of centralization, but the philosophy of management within the program is equally important. If management has a history of delegation of authority and this has worked, the logistics functions can be effectively decentralized. It is not unusual to find a country whose geography necessitates a decentralized logistics system but whose management structure rigidly adheres to centralized authority and decision-making. This is a common reason for system failure.

The three models described here and summarized in Figure VI.A.1. represent the most common organizing schemes and an understanding of these models should help planners to anticipate the strengths and weaknesses of other structures. Because the administrative structure of a program is a major determinant of the program's success, the structure should be carefully chosen.

c. Role of Committees

Certain logistics functions need the input of a variety of participants within the organization and from different ministries. This is especially true for selection and some of the tasks in utilization, such as determining standard norms for treatment. The best way to do this is to organize standing committees with responsibility for specific tasks or functions within the logistics process. Committees must be given authority for making the final decisions within their areas of responsibility. Because it is unlikely to achieve complete consensus within the ministry on the specific drugs to be included in a formulary, for example, the formulary committee should be given the authority to make final decisions, and this should remain firm. Depending on the problems encountered in any country's logistics system, other types of committees may also be needed.

2. INFORMATION SYSTEM

Reliable, comprehensive, and current information is a prerequisite for sound management and decision-making at all levels. An information system consists of records which are kept at each storage and clinical facility; forms which are used to communicate supply needs, consumption data, and other information to various offices in the supply system; and reports which summarize the data from records and forms for planning and evaluation purposes.

A good information system provides decision-makers with the information needed to make the best possible choices. The amount and type of information needed, its form, and the degree of accuracy required are, therefore, determined by the particular needs of an individual supply system.

a. Functions of the Information System

Although a Management Information System may evolve gradually as a program evolves, it should not arise haphazardly or as an afterthought. It is referred to as a system because it requires coordination with the other components of drug supply and because it requires careful planning. A Management Information System designed specifically for public drug supply programs should:

(1) Provide descriptive and quantitative information to health officials and planners about drug consumption, storage facilities, vehicles, machinery, and other available resources. This information forms the basis for supply improvements and long-range planning.

(2) Provide a tool for supervision of all personnel on a regular basis. Information on shipment receipts, drug issues, delivery times, vehicle performance, storage facilities, and other aspects of supply is useful in supervising personnel from medical stores, and supply and distribution activities. Drug consumption data also helps in advising medical practitioners.

(3) Assist in in-service education of health staff. Information itself is educational, but it is also useful in identifying areas in which specific additional training is needed.

(4) Provide data for evaluation of the quality of supply services; in some cases, such evaluations prove useful in demonstrating the impact of supply system improvements on health status.

(5) Assist in projecting future drug needs as accurately as possible in order to avoid shortages of critically needed drugs.

(6) Aid in obtaining funding for current or future budgets by documenting specific financial needs.

(7) Aid in setting priorities for supply services when funds are insufficient to provide for all possible needs.

(8) Monitor supplier performance in order to assure future selection of reliable, high quality pharmaceutical sources.

(9) Monitor drug quality throughout the supply system to help assure that patients receive safe, effective forms of the correct drugs.

(10) Plan cash flow in drug sales programs and detect losses from these programs.

(11) Provide data needed to improve the efficiency of supply services by helping to identify areas of waste and low productivity.

Although the products of an information system are often most visible at the central level, an information system should serve staff at all levels in the hierarchy, including top officials, supervisors, and operations staff (storekeepers, inventory clerks, dispensers, and others).

b. Basic Considerations in Designing the Information System

Base the Design on Information Needs at Each Level. It is easy to fall into the trap of designing record-keeping and reporting procedures that put all the burden on field staff, but address only the information needs of high-level program managers. An effective Management Information System should recognize that each level of workers (field staff, supervisors, top managers) have important, often different information needs which should be met.

Keep the System Simple. The most common error is to design a "total" information system, which includes everything that the users (and their advisors) can think of that might possibly be useful. This results in a system which is more complex than the field staff can deal with, and which collapses before it can ever begin functioning. Everyone involved may recognize that a much simpler system is essential; but there is reluctance to eliminate any of the specific data items, because each of them can be "justified" individually. Yet, experience has shown that even with a very limited range of data

included, program managers often have more information than they can usually deal with.

Allow the Information System to Grow over Time. It is important to start with the simplest, most basic system possible, particularly since the staff are learning new responsibilities. At the same time, the information system is not static; it can grow as staff members become fully accustomed to what they are already doing. It may expand to include more detailed record-keeping and reporting on existing activities, or to support new supply activities.

In summary, there are many fatal errors that can be made in the design and implementation of a Management Information System. It will be easy to omit data important to field workers, and hard to say "no" to demands for data which is useless in the field but desired by someone at the Central Ministry. The key question, at the initial stage, must be: "What information is essential, if the pharmaceutical supply system is to be a success?" Nothing else should be allowed to burden the field staff.

This raises the obvious issue: who will decide these priorities? While outside technical assistance can play a useful advisory role, the ultimate decision-making responsibility must rest with government health officials. An information system can be developed through a process of group consultation involving all users of the system ranging from officials in the Ministry of Health to the primary health workers in the rural communities. The final product will reflect a balance between the needs of the program managers, the demands of the supply system, and the capacities of the health workers. The forms and instructions developed should all be field-tested and modified to ensure that they fit the capacities of each level of health worker.

c. A Comprehensive Information System for Public Drug Supply

The elements of a drug supply information system have been mentioned elsewhere in this manual and many of the forms and records are summarized in Figure IV.A.5. Although at first glance, this list appears complex and in contrast to the principles of simplicity just outlined, it is intended as a guide rather than as a listing of essential information tools. Individual countries should tailor their information systems to their own specific needs.

Although a comprehensive information system may appear overwhelming, few facilities or offices in a given system would maintain more than two or three sets of records, and rarely would more than two or three forms flow between any two sites. Thus, for any individual in the system, the complexity is much less than it initially appears.

d. Performance Monitoring

In commercial organizations information systems are frequently used to develop performance measures with which management attempts to improve the efficiency and the success of the firm. Similar measures can also be developed for public health supply systems. Top-level health officials and

supervisors can use information to monitor the performance of the supply system and to identify areas in which improvements are needed. Performance measures can identify outstanding individual facilities or workers who are deserving of promotion, pay increase, or some other form of recognition and encouragement for continued efficiency. Finally, such information shows health officials at all levels the effects of decisions which they have made and changes which they have introduced.

Figure VI.A.2. provides an example of the performance measures which can be developed for each level in the supply system. It is useful for functional managers to establish certain expected values for these performance indices so that actual values can be compared with the expected ones. In this way it is possible to take corrective action wherever significant adverse variations are observed. Standard values for these indices depend on local conditions prevailing at the medical stores and other stocking points; hence, these values should be worked out by each program.

3. PERSONNEL

As in any health program, it is the performance of the staff which determines the effectiveness of the pharmaceutical supply system. Recruitment of qualified individuals, clear definition of job responsibilities, adequate training and preparation for specific job assignments, and regular supervision are all essential to achieve good staff performance. Personnel management is a field too broad to cover in any detail here. However, several observations related to drug supply are worthy of mention:

Job Descriptions -- For each staff member from laborer to director expectations and responsibilities should be summarized in a written job description which includes Title, Job Summary, Specific Duties, and Qualifications. Specific information about in-service training and work evaluation is also helpful.

Qualifications -- The qualifications required of job applicants must reflect a reasonable balance between the training and experience ideally needed for the job and the skills of the available work force. At the same time, there are certain skills which are basic for laborers and supervisors in a drug supply system. Language and mathematical abilities are especially important. Storemen and storekeepers who are able to recognize the different drug names and decipher package labels help assure that drugs are correctly stored and issued. Special training in this area may be needed to avoid costly stock-keeping errors.

Pharmaceutical Expertise -- In our experience, the extent to which pharmaceutical expertise is valued in medical supply programs varies considerably This is unfortunate, since the presence of graduate pharmacists and well-trained pharmaceutical assistants in top managerial and supervisory positions almost invariably improves the reliability of supply and the condition of the goods supplied. Pharmacy training usually includes information on supply management and this can be further supplemented with in-service training.

Figure VI.A.2.

Performance Indicators for a Public Drug Supply System

PERFORMANCE INDEX	EXPECTED VALUE	ACTUAL VALUE FOR PERIOD FROM: TO:
A. CENTRAL MEDICAL STORES		
1. Procurement		
(a) Supply sources: % from Asia		
% from North America		
% from South America		
% from Europe		
% from Australia		
% from any other		
(b) Value of total purchases		
(c) Types of procurements by value: % from open tenders		
% from restricted tenders		
% from direct purchase		
% from negotiated purchase		
% from donor agencies		
% from government production		
(d) Number of letter of credit extensions		
(e) Number of complete supplier defaults on confirmed orders		
(f) % of orders obtained within the lead time period		
(g) Average value of all lead times which have exceeded the expected value (in weeks)		
(h) Value of drugs rejected or discarded because of low quality (total value, value as a percent of annual issues)		
(i) Number of individual orders placed during the year		
(j) Total cost of placing orders (cost of stationery, telephone calls, cables, staff wages, overtime payments, etc.)		
(k) Approximate cost of placing an order (j/i)		
2. Wharf Clearance		
(a) Number of consignments cleared		
(b) Total value of all consignments cleared for the year		
(c) Demurrage charges		
(d) Value of damaged or lost consignments (total value and value as a percent of all drugs received)		
(e) Value of insurance claims received on these consignments (total value and value as a percent of damaged or lost consignment)		
3. Inventory Control		
(a) Value of average inventory on hand		
(b) Value of average monthly and annual consumption		

Figure VI.A.2. (continued)

PERFORMANCE INDEX	EXPECTED VALUE	ACTUAL VALUE FOR PERIOD FROM: TO:

(c) Average inventory on hand as months of consumption (a/b)

(d) Number of stockouts*

(e) Length of complete stockout situations (in weeks)*

(f) Instances of total airfreight deliveries (number & percent of all deliveries) (should exclude any drugs which are ordered by air-freight on a regular basis)

(g) Value of outdated drugs per year (total value and value as percent of drugs used)

(h) Average inventory on hand as a percent of annual issues

4. Storage

(a) Value of drugs lost due to poor handling and storage conditions (total value, value as percent of annual issues, value as percent of average inventory)

(b) Value of drugs pilfered or declared unaccountable (total value, value as percent of annual issues, value as percent of average inventory)

B. REGIONAL AND DISTRICT MEDICAL STORES

1. Requisitioning/ Purchasing

(a) Total value of requisitioned drugs (receipts from central medical stores)

(b) Number of individual orders placed for drugs from the Central Medical Stores during the year

(c) Cost of placing orders (cost of stationery, telephone calls, staff wages, overtime payments, etc.)

(d) Approximate cost of placing an order (c/b)

2. Inventory Control

(a) Value of average inventory on hand

(b) Value of average monthly consumption

(c) Average inventory on hand as months of consumption (a/b)

(d) Number of stockouts*

(e) Length of complete stockout situations (in weeks)*

(f) Instances of emergency deliveries (number & percent of all deliveries)

(g) Value of out-dated drugs (total value, value as percent of annual issues, value as percent of average inventory)

3. Storage

(a) Value of drugs lost due to poor handling and storage conditions (total value, value as percent of annual issues, value as percent of average inventory)

PERFORMANCE INDEX	EXPECTED VALUE	ACTUAL VALUE FOR PERIOD FROM: TO:

(b) Value of drugs pilfered or declared unaccountable (total value, value as percent of annual issues, value as percent of average inventory)

C. REGIONAL AND DISTRICT HOSPITALS

1. Inventory Control

(a) Value of average inventory on hand

(b) Value of average monthly consumption

(c) Average inventory on hand as months of consumption (a/b)

(d) Number of stockouts*

(e) Length of complete stockout situations (in weeks)*

(f) Instances of emergency deliveries (number & percent of all deliveries)

(g) Value of out-dated drugs (total value, value as percent of annual issues, value as percent of average inventory)

2. Storage

(a) Value of drugs lost due to poor handling and storage conditions (total value, value as percent of annual issues, value as percent of average inventory)

(b) Value of drugs pilfered or declared unaccountable (total value, value as percent of annual issues, value as percent of average inventory)

3. Issuing and Dispensing

(a) Value of drugs issued to health centers, aid posts, etc.

(b) Value of drugs issued to outpatient departments and in-patient units

(c) Total value of issues (a + b)

(d) Outpatient Index: (value of drugs issued to all out-patient departments) (number of outpatients treated)

(e) Inpatient Index: (value of drugs issued to all in-patients) (number of inpatients treated)

D. HEALTH CENTERS AND HEALTH POSTS

1. Inventory Control

(a) Value of average inventory on hand

(b) Value of average monthly consumption

(c) Average inventory on hand as months of consumption

2. Dispensing

(a) Value of drugs dispensed

(b) Patient Index: (value of drugs issued) (number of patients treated)

* Indices may be divided by VEN category (Chapter VI.B.) to assess impact on vital drugs.

Coordination of Authority and Responsibility -- Activities involved in the supply process frequently cut across program lines and staff members may be subject to multiple and sometimes conflicting orders. In designing job descriptions care must be taken to avoid such overlap and potential for conflict. Where overlap exists, the job descriptions need to be reviewed by all the programs involved.

In-Service Training programs can substantially improve the performance of employees by upgrading their skills and by teaching them the specific skills and procedures involved in pharmaceutical supply (see Chapter VI.D.).

Staff Motivation -- Conscientiousness and industriousness contribute greatly to program effectiveness. Staff motivation may be stimulated by many factors, including a sense of achievement, personal recognition, belief in the value of the work itself, sense of responsibility, the opportunity for advancement and pay*. The opportunity for advancement and reasonable levels of compensation are of particular importance. For this reason career ladders which specify paths for increasing status and pay are important.

Image of Supply Management -- Sufficiently high status must be granted to top-level managers and supervisors in logistics services to attract competent leadership. Supply management too frequently is given low standing and, as a consequence, substantial waste results from mismanagement by incompetent staff.

Guiding the Supply-Related Activities of Health Workers -- For most health workers, supply-related activities are only one part of their many responsibilities. Rather than writing a second job description or trying to incorporate supply activities into the primary job description, it is helpful to simply prepare a checklist of supply-related activities which health workers are expected to perform. This establishes expectations for health workers, but more importantly, it can serve as a tool for training and supervising village health workers in supply activities. Figure VI.A.3. is an example of a checklist prepared for health promoters in a rural health project in South America. Such a list can readily be included in field manuals, where they exist.

a. Staffing a Pharmaceutical Logistics System

Staffing patterns for supply management are as many and as varied as the programs involved. The range of participants and variety of staff positions at each level of the system are illustrated in Figure VI.A.4.

The administrative linkages between government participants also vary. Selection and use activities may fall within the Ministry of Health, while procurement and distribution may be handled by a separate ministry responsible for government supplies. There are also many options in terms of linkage with

---

* Adapted from McMahon, 1980.

Figure VI.A.3.

Supply Activity Checklist for Health Promoters

1. Each time you see a patient make an entry in the Health Register. If you issue or sell a medicine, record its name, the number of units, the price per unit and the total price in the appropriate columns. Price information is found on the Official Price List.

2. Record all information before each patient leaves. Do not wait because you will forget. Also, record the information directly on the Register. If you record it on small scraps of paper, with the idea of transferring it to the Register later, the scraps of paper may get lost.

3. After each patient leaves, put the money for the price of the medicine in one envelope and put the money for the Community Profit in another. The profit for each sale is precalculated and is found at the end of the Official Price List.

4. Once a week, you should meet with the Community Health Committee Treasurer to review the Register and turn over the money from sales and the Community Profit.

5. Once a month, you should meet with the Community Health Committee Treasurer to prepare the Community requisition. Note that for each supply you may request only the amount used during the preceding month.

6. After the requisition is prepared, the Treasurer should turn over to you the total amount of money collected from sales during the preceding month.

7. Take the requisition, the money, and your Health Register to the health post. It is best to put the money in a sealed envelope.

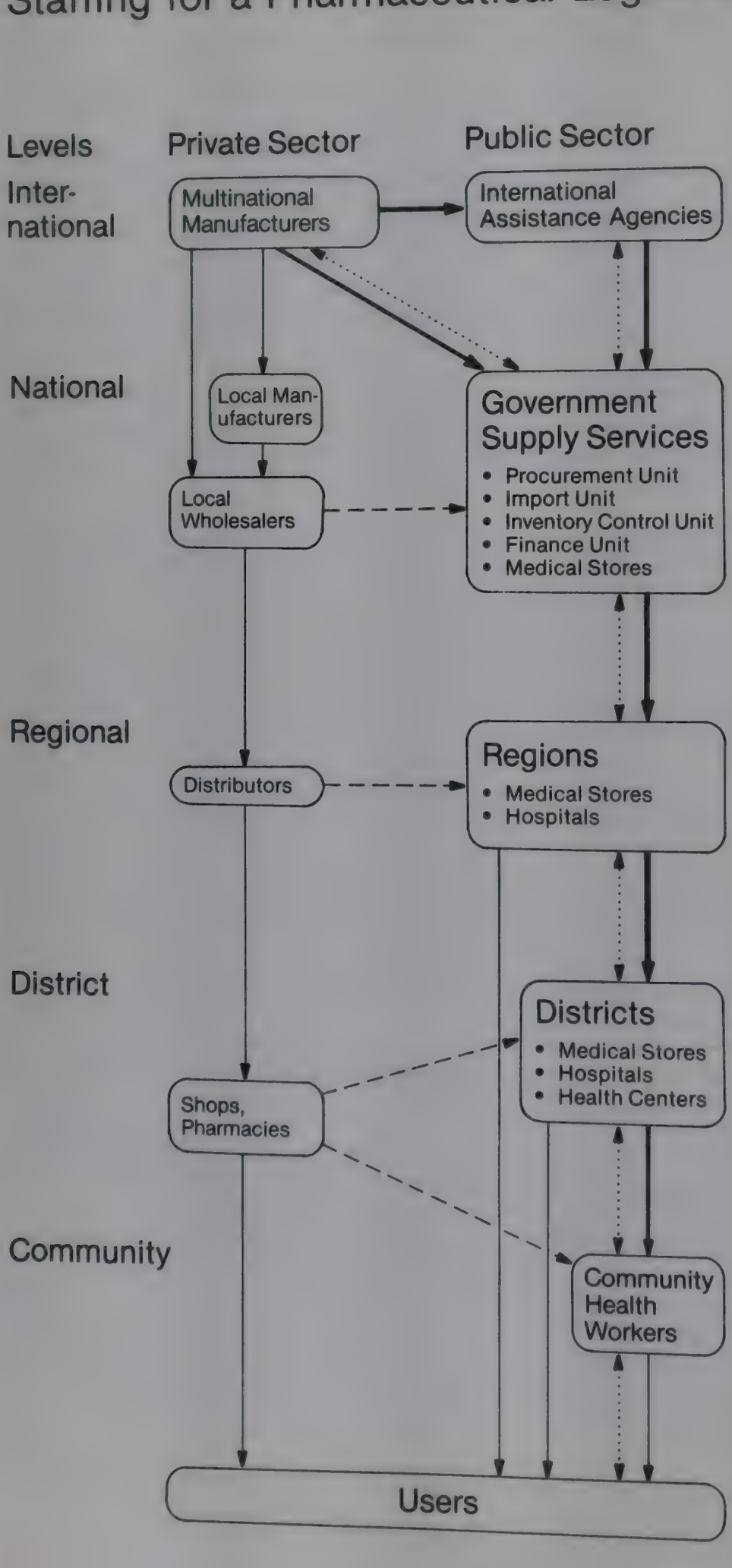
8. Turn the requisition and the money over to the auxiliary in charge of supplies at the health post. She will turn over or "sell" to you an amount of drugs of equivalent value to the money you turn in. Note that if prices have gone up, you may receive slightly less of a certain product for your money than in previous months.

9. When your drugs and other supplies are ready, the person at the resupply point will give you a bill from the area hospital (receipt for the order). Together with this person, check all the supplies to make sure that they are equal with the amount shown on the bill. When everything is in order, sign the bill and take one copy, plus the supplies, back to your community.

10. When you arrive home in your community, review the bill and count the supplies once more with the Treasurer. Then store the supplies neatly in your house. Take care to see that they stay clean and dry.

Figure VI.A.4.

Staffing for a Pharmaceutical Logistics System



SELECTION
- Chief of Health Services
- Chief of Planning
- Program Directors
- Health Educators
- Pharmacists
- Auxiliary Health Workers
- Government Agencies Served by the Drug Supply System

PROCUREMENT

FINANCE
- Director of Finance
- Chief Supply Accountant
- Supply Accountants I,II

PROCUREMENT
- Director of Procurement
- Chief Order Clerk
- Order Clerks I,II
- Typists (bilingual)

EXTERNAL AFFAIRS
- Director of Foreign Exchange

DISTRIBUTION

IMPORTATION
- Import Manager
- Customs/Insurance Clerks
- Drivers, Laborers

INVENTORY CONTROL
- Director of Inventory Contro
- Chief Inventory Control Cler
- Inventory Control Clerks I,I

MEDICAL STORES
- Director of Medical Stores
- Chief Storekeeper
  Assistant Storekeeper
  Storekeepers I,II
  Storemen (laborers, porter
- Chief of Shipping and Receiv
  Shipping/Receiving Clerks
  Storemen (laborers, packer
- Chief Security Officer
  Security Officers (Guards)

DISTRIBUTION
- Director of Distribution
- Vaccine Distribution Manager
- Transport Manager
- Drivers, Mechanics, Laborers

USE

HOSPITAL PHARMACIES
- Pharmacist
- Pharmaceutical Auxiliaries
- Dispensers

HEALTH SERVICES
- Program Supervisors
- Vaccine Officer
- Medical Officers
- Nurses
- Auxiliary Medical Workers
- Dispensers

COMMUNITY
- Village Health Workers

drug supply sources. If the primary source of pharmaceuticals is bulk procurement at the national level by a government agency, then all of the jobs listed in Figure VI.A.4. must be performed by government staff. On the other hand, if the central procurement office acts only to negotiate with commercial suppliers for direct deliveries to health facilities, then most of the government distribution jobs will be eliminated; importation, bulk inventory control, and bulk storage will occur in the private sector.

Whatever the organizational structure and contractual arrangements which define the supply system, all of the tasks reflected in the jobs listed in Figure VI.A.4. must be performed if drug supply is to occur efficiently and reliably.

b. Manpower Planning and Development

To provide the manpower needed to fill the positions described in the previous section, it is necessary to plan for the recruitment, selection, training, and supervision of adequate numbers of qualified personnel. Manpower planning is a specialized area which requires that knowledgeable individuals perform a systematic analysis and formulate a comprehensive plan. The major steps in manpower planning are as follows*:

(1) Prepare for manpower planning by assembling representatives from appropriate health service organizations into a manpower planning group.

(2) Analyze existing manpower and current supply services.

(3) Determine future manpower requirements in terms of the numbers, qualifications and training, and distribution of personnel.

(4) Estimate the future manpower supply based on current numbers, rates of leaving, and expected sources of new staff.

(5) Identify and resolve mismatches between the expected requirements and estimated supply of manpower, either by adjusting the requirements or by increasing the supply.

(6) Develop a detailed manpower strategy and implementation plan which includes a schedule of activities and an assignment of specific manpower development activities.

The major component of any manpower development plan will be the training programs. Training for pharmaceutical logistics is discussed in detail in Chapter VI.D.; Designing Training Programs to Improve Pharmaceutical Logistics. In planning for future manpower needs and the requisite training programs, it is useful to recognize the following three types of training programs:

Start-Up Training Programs -- In the early phases of a new or rapidly expanding program, special training programs are sometimes required to

---

* Based on Hornby et al., 1980.

teach a large number of individuals in a limited period of time. Caution must be exercised not to abbreviate the content of the curriculum to the extent that the new staff, after training, are unable to handle all of their basic tasks.

Entry Level Training Programs -- Once a program is established and manpower requirements are predictable, new personnel should expect to receive basic, standardized training for their jobs. The capacity of entry level programs should be sufficient to accommodate staff losses to retirement and job transfers as well as program expansion.

In-Service Training Programs -- Maintenance of staff performance and up-grading of staff skills are dependent upon in-service training programs. Such programs are particularly important for maintaining an adequate pool of qualified staff for promotion to middle and senior management positions.

c. Importance of Routine Supervision

Hiring and training competent staff is only the beginning of the on-going process of personnel management. Routine supervision is a part of the process which is essential for continued program effectiveness. Personnel need to be encouraged in the activities they are performing well, and advised in areas that need improvement.

Supervision should be a means not only of reviewing staff performance in technical and administrative functions, but also of uncovering and solving problems and motivating staff. Effective supervision requires the following conditions*:

(1) A well-defined supervisory structure and adequate supervisory personnel. Supervisory responsibilities should be clearly specified in job descriptions. Calculation of supervisory ratios (number of subordinates to number of supervisors) will help in assessing the adequacy of supervisory personnel.

(2) Adequate incentives for regular supervision. Written schedules, reporting of supervisory activities, and consideration of supervision performance in promotion decisions may all serve as inducements. Provision of travel and daily allowances for supervisory visits are often essential to assure regular visits.

(3) Goals for supervision. Supervisors who are given a clear understanding of the purposes of their supervisory activities are more likely to devote sufficient time and energy to supervision and to perform effectively.

(4) Clearly established and sufficient frequency and length of sessions with subordinates. Supervisors can be more conscientious in their duties if provided with specific guidelines for the quantity of supervision needed.

---

* Adapted from Vaidya, 1979.

(5) Appropriate and clearly specified content of supervisory activities. The work of supervisors is greatly aided by written supervision instructions, guidelines, and checklists.

Country Study VI.A.3. presents the results of an analysis of supervision in one country's health programs. Although the discussion concerns health services in general, many of the observations are useful in considering supervision of logistics personnel. This study also describes an important technique for encouraging regular, effective supervision: pushing supervision down from above. Unit chiefs, directors, and other health officials at central levels in the logistics system who regularly visit the regional medical stores and hospitals will induce regional officials to visit district facilities and so on. Advisors to government projects can themselves help establish high expectations for supervision by traveling with government counterparts to peripheral facilities.

The value of regular, systematic supervision of subordinates at all levels of the system cannot be overemphasized. Continued effectiveness in the areas of strength, and improvement in the areas of weakness depend upon this supervision.

4. FACILITIES, EQUIPMENT, AND SUPPLIES

a. Facilities

Pharmaceutical management is one health system component where adequate office facilities for central administration and appropriate storage units for supply protection are essential.

Administrative Offices -- Drug system management rests largely on the ability to maintain and utilize many types of records generated in the supply process. While nothing elaborate is required, adequate space for files (orders in process, historical files of supplier data such as tender schedules, quality control, and past invoices, utilization and authorization records for in-country user institutions) and sufficient desks and typewriters to process current work are essential. Inadequate space, equipment, and office planning reflect low priority put on pharmaceuticals and, by frustrating the work of pharmaceutical supply staff, lead to inefficient use of other resources.

Medical Stores -- Central, regional, and local medical stores have largely similar requirements for security, organization, and specialized storage such as cold rooms and freezers; they differ from each other primarily in scale. The frequent temptation to use a local hospital as the area medical store must be balanced by the real risk of diversion of limited stocks allocated for rural units. Even when new facilities are not possible, layout and organizational revisions of existing structures are worth consideration. Details of storage requirements are discussed in Chapter IV.D.

b. Equipment

Vehicles are the biggest bottleneck in many distribution systems, with

Country Study VI.A.3.

A Study of Health Worker Supervision in Nepal

In Nepal, supervision of health workers is considered an essential goal in providing health services. A recent review of the Integrated Community Health Project (ICHP), the Family Planning and Maternal and Child Health Project (FP/MCH), and the Malaria Project provides some insights into how this goal is realized.

Amount of Supervision -- Supervision is based on a well-defined structure of supervisory levels and offices. Standard supervisory ratios (number of subordinates to supervisor) have not been developed in Nepal, but were found to vary in practice from 34 field staff per district supervisor in the Malaria Project to 2.5 field staff per post supervisor in the ICHP. Ratios seemed to depend on the type of program, the level (district versus post), and other factors.

Although adequate supervisory ratios are prerequisites, effective supervision also depends on adequate incentives for supervisors. Supervisory schedules and expense allowances appeared to play an important role in assuring regular supervision. At the district level written schedules were routinely present only in the Malaria Project, but at the post level they were usually available for all programs. Delayed payment of travel allowances and insufficiency of these allowances were felt to be significant problems by over half of the supervisory personnel, but this was less true in the Malaria Project. These results led officials to expect that greater supervision would be provided by the Malaria supervisors. Survey results confirmed this expectation: At the district level, 70% of the Malaria Project offices received 6 or more supervision visits per year versus 25% for the FP/MCH offices and 5% for the ICHP offices. Results at the post level were similar.

In reviewing the supervisory patterns, it was observed that the Malaria Project tended to "push supervision down from above". That is, if supervisors from upper levels went frequently to the district level to supervise, district supervisors were induced to go to the post level more frequently and, in turn, post level supervisors were pushed to spend more time in the field. Less frequent supervisory visits in the Integrated Community Health Project were felt to reflect, in part, a lack of central and regional supervisors in that project.

Content of Supervision -- The existence of specific written or verbal supervision instructions, guidelines, or checklists varied from program to program. Health Officers at the district level and all supervisory personnel at the post level were felt to have inadequate instructions. This inadequacy is only partly reflected in the extent to which supervisors left written records of their supervisory sessions. The existence of written recommendations and comments left by supervisors for subordinates to refer to also varied among the different programs, as shown below.

	Existence/Type of Instructions for Supervisor				Written Record Left by Supervisor	
	Written %	Oral %	None %	NR %	Yes %	No %
District Level						
District Health Office	21	11	68	0	47	53
District Family Planning Office	75	8	17	0	65	35
District Malaria Office	79	21	0	0	99	1
Post Level						
Integrated Health Post	30	20	20	30	82	18
Family Planning Clinic					36	64
Malaria Unit Office	28	22	39	11	94	6

The content of supervisory sessions could be divided roughly into specific technical and administrative instruction and non-specific praise, dissatisfaction, and general comments. The more specific types of instruction appeared to be more effective in achieving beneficial changes in staff performance.

Conclusion -- This review of supervisory activities demonstrated to government officials that significant variations in supervision existed among public health programs. Important factors in effective supervision were found to be (1) provision of adequate incentives, including schedules and expense allowances, (2) formulation of specific guidelines (preferably written) for the content of supervisory sessions, and (3) preparation of written comments for subordinates at the end of each session. (1977)

high maintenance costs, scheduling problems, and rapidly rising operational expenses as fuel prices escalate (see Chapter IV.E). Public systems tend to utilize only government vehicles for transport, but skyrocketing costs should encourage greater consideration of the private sector for distribution to major stocking points. Trucking lines, buses, and taxis penetrate far into most rural areas and offer important alternatives or supplementary mechanisms for delivery, without the headaches of scheduling, drivers, and maintenance.

Another intermediate step is to reimburse other health programs or even other ministries for scheduled use of their vehicles. Chapter IV.E. should be referred to for further discussion of delivery strategies.

While small and inexpensive computers are rapidly becoming useful office tools in many drug supply programs, effective use of the manual systems -- file cabinets, card files, and the typewriter -- are still far more important. Many medium-sized programs can function quite adequately with manual systems. Mastery of the basic organizing and communication tasks is a prerequisite in any case to incorporating a computer into the information system.

Some programs have a tradition of using folders stored on shelves in stacks or in storage cabinets. In general, these approaches do not work as well as standard file cabinets and should be avoided.

c. Expendable Supplies

The drug supply system really involves only two basic commodities: the medicines themselves and the paper that controls drugs in the shape of forms, ledgers, stock cards, and procedure books. Analysis often reveals ways in which the forms and papers involved in procurement process management can be reduced in number or made more concise. The forms, like the packaging and labeling of the drugs themselves, are signals to the users of the importance of the supply process. Sloppy forms, poor paper quality (leading to fragmented records), and haphazard design can create hidden costs and system failures that are largely preventable. Stockouts of essential record cards can be as bad as (or can lead to) stockouts of essential drugs. It is often false economy to cut corners on the design, quality, or availability of support supplies.

5. FINANCIAL MANAGEMENT

Financial management is a complex and specialized area which requires qualified and experienced managers, accountants, and other personnel. The details of financial management vary from country to country; however, there are several specific observations which can be made about financial management as it applies to public pharmaceutical supply. Some of these observations were made earlier in Chapter III.E. and detailed descriptions of some aspects of logistics financing can be found in that chapter. Descriptions of the budgeting process also appear elsewhere (Chapters I.C. and III.E.). A more comprehensive discussion of public enterprise financing is beyond the scope of this manual, but the following observations may be of value.

a. Development versus Operating Budgets

In both the chapters on planning (I.C.) and financing (III.E.) a distinction was made between development funds and operating funds. Development funds are generally one-time investments made when a program is initiated or substantially expanded. Operating funds are required for the day-to-day expenses incurred in an existing program, including funds for procuring additional drug supplies.

Clear distinction between development and operating funds is important for planning and budgeting. Often special funding is available for development activities through international assistance agencies and bilateral aid programs. A clear presentation of funding needs for project development should help in acquiring such aid.

Distinction between these two major budget categories is also important because development investments have a significant impact on future annual operating budgets. In contrast to highway construction projects, in which the initial investment is large compared with the operating expense, drug supply systems generally require large annual expenditures, even after moderate initial investments. For example, a system in which the supply "pipeline" is stocked with U.S.$2 million in drugs, for an anticipated consumption of $1 million per year (pipeline of 24 months worth of consumption), may find that within a few years the annual operating budget has risen several million dollars because of rapidly increasing demand and rising drug prices.

b. Procurement Cycles and Fiscal Cycles

Efficient, economical procurement policies are sometimes hampered by government fiscal policies. For example, even though there are many drawbacks to acquiring drugs through one large annual purchase (see Chapter III.B.), this type of procurement is essentially mandated by government policies which state that the contractual commitment of funds and the payment of funds must occur within the same fiscal year. With lead times usually exceeding six months and often exceeding twelve months, this type of policy makes anything but single annual purchasing virtually impossible.

There are other examples of ways in which government policies concerning fiscal cycles conflict with efficient logistics management. Where such conflicts are noted, officials responsible for drug supply should consider efforts to amend the government policies. Such amendments have been successfully pursued in several countries and significant improvements in supply efficiency and reductions in cost have resulted.

c. "Free" Drugs

It has been previously noted that the popular policy of providing drugs without charge to patients served by government health workers is fraught with difficulties. Few, if any, of the programs which promise free services meet expectations. The result is that the public is frustrated by inadequate services and government health workers are dispirited by trying to work without

resources. At the same time the people demonstrate their willingness to pay for something they value by spending money on drugs obtained in the bazaars, on street corners, or in shops. Village surveys have demonstrated that -- at least in some countries -- even the rural poor spend significant amounts of their very limited cash resources on drugs.

The resolution of this paradox is inevitably a local and highly political task. But, certain compromises appear attractive. For example, charging for curative services -- for which people are more willing to pay -- would permit the government to allocate resources to the more cost-effective preventive services (immunizations, epidemic control) -- for which people are not so willing to pay.

d. Accountability to Donor Agencies

International assistance agencies, bilateral aid programs, and other donors frequently have special requirements regarding the use of their funds. Procurement may be directed to certain commodities or certain sources; distribution may be limited to certain facilities (e.g., non-hospital health services); use may be restricted to certain groups (e.g., pregnant women).

If the recipient is required to show compliance with such special requirements, it is much easier to plan accounting procedures in advance than it is to attempt to locate the information after the fact. Therefore, financial managers should make themselves aware of any special reporting requirements and modify the information system accordingly.

e. Foreign Exchange Limitations

Most developing countries are still highly dependent upon foreign suppliers of drugs and raw materials. In countries where imports are restricted by government foreign exchange controls, this dependency places public drug supply in jeopardy. It is therefore incumbent upon the procurement staff to seek the best buys and most economical payment terms possible. In this regard, it may be highly advantageous to spend available domestic funds to hire well-qualified procurement staff in order to achieve the wisest use of more limited foreign exchange funds.

Local importers may have their own methods (occasionally illicit) for "stretching" foreign exchange allocations.

f. Over-Requisitioning by Health Facilities

In some government supply systems, the administrative linkages between the financial unit, the procurement unit, the medical stores, and the health facilities are such that individual health facilities are able to requisition and receive quantities of supplies which exceed their budget allocations or, depending on the fiscal arrangements, their ability to reimburse the central fund. In some settings this excessive use of drug supplies proves to be an effective device for exacting greater allocations from the government or donor agencies; faster consumption of drugs leads to near shortages, for which "emergency" allocations are made.

Unfortunately, when the financial resources are strictly limited, the result of over-requisitioning by some facilities is lack of drugs at other facilities or mid-year stockouts at the central medical store.

Therefore, programs which operate on a fixed budget need to establish drug accounting procedures which will hold individual health facilities responsible for their drug requests. This type of institutional accountability can be achieved in many ways. For example, in some systems each drug is given a price (usually the C.I.F. price with or without an additional surcharge to cover operating costs) and whenever a requisition is filled the cost of the supplies is calculated. This amount is then subtracted from an "account" which is established for each institution or, if the funds come from the institution, a bill is sent.

Regardless of the operational details, effective linkages should exist between financing, procurement, and distribution functions. These linkages are to ensure that unexpected shortages from uncontrolled requisitioning of supplies do not occur.

g. Cash Flow in Drug Sales Programs

Factors which contribute to the failure of revolving drug funds were summarized previously (see Figure III.E.8. in Chapter III.E.) and need not all be repeated here. However, the importance of steady cash flow in drug sales programs is worthy of emphasis.

Low return of funds from health facilities may result from several factors. There are often many steps required for the transfer of funds from a peripheral facility to the central bank; some health facilities may simply be deficient in depositing their collections, leading to losses of revenue which are sometimes unrecoverable; and government financial officials, for whom drug sales programs may represent an unconventional and confusing innovation, may create unnecessary lags in cash flow.

Before establishing a drug sales program, such impediments to dependable cash flow should be anticipated to the greatest extent possible. Policies and procedures to maximize the efficiency of cash flow can then be negotiated in advance.

h. Staff Salary Levels

A major concern of staff in any organization is that of wages and salaries. In public drug supply systems the staff handle items which are highly attractive to black market distributors. The diversion of drugs to these markets can create significant disruptions in regular supply to health facilities. Thus, because temptation is greater in the face of low salaries, higher wages may be necessary simply to facilitate dependable supply.

Furthermore, because the value of drug products is high in local terms, the expertise of highly qualified and experienced procurement and supply management staff is needed to "stretch" the limited available funds. Obviously, adequate salaries can help to keep these individuals in the service of the government.

SUMMARY

The components or building blocks for supply management are (1) organizational structure, (2) information system, (3) personnel, (4) facilities, equipment and supplies, and (5) financial management.

The organizational structures found in pharmaceutical supply programs are:

- Centralized -- drug supply is managed by a separate pharmacy or logistics unit at the central level;
- Directorate -- a separate logistics unit coordinates logistics activities, while performance of activities remains decentralized;
- Decentralized -- each government program and sometimes facility is responsible for its own selection, procurement, storage, and use of drugs.

These systems can be compared in terms of (1) the image and prestige they afford supply activities, (2) their potential for economies of scale, (3) their use of staff and development of staff specialization, (4) communication and coordination, and (5) their possible influence on utilization patterns.

A simple, but comprehensive information system is a prerequisite for procurement and distribution. It should record drug and cash flow, provide information for in-service training and for staff evaluation, and produce data which can be used for projecting future demand.

Personnel management involves hiring qualified staff, providing necessary training programs, ensuring routine supervision, working to motivate staff, and planning for future manpower requirements.

Facilities, equipment, and supplies are frequently neglected, but vital components of drug supply. Attention to these elements can improve efficiency of procurement and distribution.

Financial management for drug supply activities requires consideration of the following factors:

- Development versus operating costs;
- Procurement cycles and fiscal cycles;
- Problems with "free drug" policies;
- Accountability to donor agencies;
- Implications of cash flow delays.

CHAPTER VI.A. REFERENCES

Hoey, J.M. et al: Building the Supervision System - Experiences from Nepal. Presented at the Conference of the National Council on International Health, Washington, D.C., 1981.

Hornby, P. et al: Guidelines for Health Manpower Planning. Geneva: World Health Organization, 1980.

McMahon, R. et al: On Being in Charge - A Guide for Middle-Level Management in Primary Health Care. Geneva: World Health Organization, 1980.

United Nations: Organization, Management, and Experience of Public Enterprises in Developing Countries. New York: United Nations, 1974.

United Nations: Supply Management: Towards Better Use of Equipment and Material Resources in Developing Countries. New York: United Nations Department of Economic and Social Affairs, ST/ESA/SER.E/16, 1978.

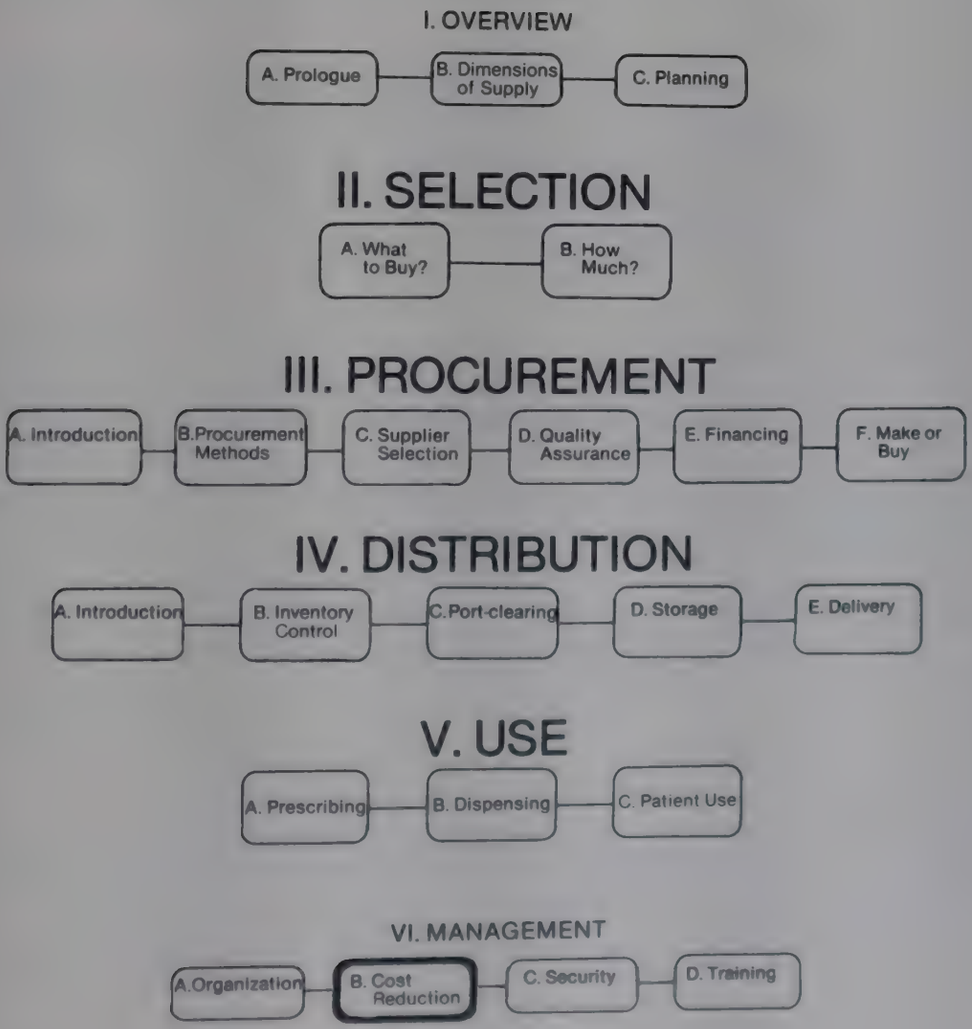
UNICEF: Hygeia, 2nd Edition. New York: UNICEF, 1964.

UNICEF: RANI Guidelist. New York: UNICEF, 1975.

Vaidya, B.N.: Mid-Term Health Review 2035. Kathmandu, Nepal: His Majesty's Government, Ministry of Health, 1979.

Chapter VI.B.

Systematic Cost Reduction



	Page
1. EFFECTIVENESS, EFFICIENCY, AND COST REDUCTION	493
2. USING THE VEN SYSTEM TO SET PRIORITIES	495
a. Guiding Purchases with the VEN System	497
b. Setting Safety Stock Levels with the VEN System	498
c. Other Applications of the VEN System	498
3. ABC VALUE ANALYSIS	500
a. Performing an ABC Value Analysis	500
b. Using ABC Analysis to Guide Procurement Patterns	500
c. ABC Analysis and Delivery Schedules	503
d. Using ABC Analysis to Seek Lower Prices	504
e. Assignment of Staff	504
f. Stock-Taking	504
4. LEAD TIME ANALYSIS	504
5. REDUCING WASTE FROM EXPIRED PRODUCTS	505
a. Avoiding Short Shelf-Life Stock	505
b. Handling Short Shelf-Life Drugs	508
6. PIPELINE ANALYSIS	509
SUMMARY	510
REFERENCES	511

Systematic Cost Reduction

Virtually all of the preceding chapters deal with activities which, in one way or another, influence the cost of supplying pharmaceuticals. Careful selection, wise procurement, efficient distribution, rational use, and sound management should all serve to minimize cost. Nevertheless, there are specific cost-saving activities which can contribute to economical drug supply. Many have already been discussed, but several techniques have been touched on only briefly.

This chapter will begin with a general discussion of effectiveness, efficiency, and opportunities for cost-saving. Then, several specific strategies will be discussed in detail. They are intended to supplement the activities of a supply system which is already functioning. None of the ideas can be used unless this basic system is already in operation.

1. EFFECTIVENESS, EFFICIENCY, AND COST REDUCTION

The effectiveness of a drug supply system is the degree to which it provides required services. One measure of effectiveness is the service level, or the percent of time specific drugs are available at specific health facilities. The converse of this measure is the stockout rate; the more frequent and longer the stockouts, the less effective the supply system.

Efficiency is the degree to which effectiveness is achieved while simultaneously holding down costs. It should be noted that an ineffective drug supply system will never be efficient. Efficient supply systems must be both effective and relatively inexpensive. Measures of efficiency are not so easy to calculate. One measure frequently used is the ratio of the supply system's operating costs to the costs of the drugs flowing through it. A major drawback to this measure is its use of procurement costs of drugs; the more expensive the procurement price the more efficient the system appears to be. A better measure of efficiency may be the total cost of delivering a course-of-therapy to the patient, regardless of who pays. This cost can then be compared to alternative systems, such as private sector pharmacies, or similar drug supply systems in other countries.

Neither of these efficiency measures, however, has anything to do with effectiveness. They ignore the hidden costs that ineffectiveness can introduce. For example, inadequate resources allocated to training and supervisory support can prevent drug supply systems from functioning properly by leading to underutilization of health facilities and their staffs, thereby "wasting" those resources.

When attempting to measure efficiency, such hidden costs should be added to the direct costs of the drug supply system. Any supply system which incurs hidden costs in excess of the cost of improving effectiveness (which would eliminate those hidden costs) cannot be called efficient. Stockouts, for example, introduce hidden costs, but these are not easy to estimate. They

include underutilization of other expenditures, as well as the costs incurred by patients in unsuccessfully seeking treatment at the undersupplied facility and the additional costs of having to seek services elsewhere.

Conversely, however, if an expenditure can be reduced without affecting the effectiveness of the supply system, the resulting system will be more efficient, since it supplies the same level of service at a reduced cost. For example, analysis of procurement records may indicate that deliveries of drugs are never received more than three months late and, therefore, the 6 month safety stock held at the central warehouse can be cut in half.

The major categories of expenditure for a supply system are discussed briefly below, with respect to their potential for cost-saving.

Procurement -- Drug procurement costs are usually the biggest single item in a drug supply system budget. As discussed in earlier chapters, significant savings can frequently be made in procurement by procuring a greater proportion of generic drugs, by purchasing in bulk quantities, by reducing the number of therapeutically equivalent drugs, and by improving procurement procedures to encourage competition.

Inventory Levels -- It may be possible to shorten the supply pipeline by reducing safety stocks and working stocks, and/or shortening the procurement process. A 10% reduction in the length of the pipeline will permit a 10% increase in the monthly delivery capacity of the system with no additional capitalization. Or, if additional monthly capacity is not needed, the capital locked up in the pipeline can be drawn off in the form of reduced purchases during the year the pipeline is shortened.

Delivery -- Transportation costs are frequently a major cost. More effective scheduling and routing may yield significant savings. If delivery intervals are lengthened, however, the transport savings may be lost to higher inventory holding costs.

Personnel -- Salaries are frequently the second largest item in the drug supply system budget. Civil service positions are usually hard to create and, once created, hard to eliminate, at least during any given financial year. Day labor and contract positions are less fixed in nature and may, however, present opportunities for savings in the short run.

Facilities and Equipment -- Infrastructure costs are the most difficult to reduce. Once warehouses have been built and transportation, packaging, and cold chain equipment purchased, the supply system manager has little choice but to operate those facilities. Thus, development expenditures and their implications for operating costs deserve emphasis (see Chapter III.E.). For example, on one Caribbean island, the fuel cost for kerosine refrigerators has been estimated at U.S $0.60 per day while the corresponding cost for gas refrigerators is only $0.25 per day. At these rates each gas refrigerator costs $127 less per year to operate. In addition, the gas refrigerators are easier and less expensive to maintain. Faced with this information, the government might request foreign donors to provide only gas-fueled refrigerators, and should probably consider turning down offers of kerosene refrigerators, even if it means buying its own gas refrigerators.

In many drug supply systems these simple cost-cutting approaches may be all that is necessary to achieve significant gains in efficiency. Especially where new drug supply systems are being installed or where old ones are undergoing major alterations, there is likely to be insufficient data on which to base an in-depth economic analysis of alternatives. These systems should be designed with larger than normal safety stocks and perhaps extra transport capacity, which can later be cut back, if experience indicates surplus stocks or capacity.

But whenever possible analysis of operating systems can and should be based on hard evidence. Purchase records should accurately reveal the average length of time between issue of letters of credit and shipment of drugs, as well as the amount of time the drugs spend in transit. The information system should yield accurate estimates of the inventories held at different levels in the supply system, and the length and frequency of stockouts at both warehouses and health service facilities. These same sources can also provide the information needed to estimate expected variances in both supply and demand so that the safety stocks necessary to assure a given level of effectiveness can be calculated rather than guessed.

2. USING THE VEN SYSTEM TO SET PRIORITIES

One way to maximize the efficiency of the health system when funds are limited is to set procurement and stock-keeping priorities according to the potential health impact of individual drugs. A method of doing this is the VEN system, in which all of the drugs on the supply list are placed into the following three categories:

V -- VITAL drugs which are potentially life-saving, which have significant withdrawal side-effects such that regular supply is mandatory (for example, in high dose propranolol or steroid therapy), or which are included in basic health service drug lists (especially vaccines);

E -- ESENTIAL drugs which are effective against less severe, but nevertheless significant forms of illness;

N -- NON-ESSENTIAL or normal usage drugs for minor or self-limited illnesses, drugs which are of questionable efficacy, and drugs which have a high cost for a marginal therapeutic advantage.

Figure VI.B.1. provides some sample guidelines for establishing VEN categories. In light of the health care implications of using such a system, development of the categories is probably best done by a committee of eminent medical personnel. The classification should be decided primarily on the basis of the health impact of individual drugs. Unit prices and popularity of medications should have little, if any, influence on the process.

The VEN system was developed in Sri Lanka, where it was first applied to importations by the State Pharmaceuticals Corporation. All drugs procured by the Corporation were reviewed by a clinical pharmacologist and assigned to one of the three categories. A sample of the drugs classified by this method is given in Figure VI.B.2.

Figure VI.B.1.

Sample Guidelines for VEN Categories

Characteristic of Individual Drugs	Vital(V)	Essential(E)	Non-Essential(N)
Occurrence of Target Condition(s)			
Persons Affected (% of population)	>5%	1-5%	<1%
Persons Diagnosed (cases/ 100,000 population/year)	200	50-100	50
Persons Treated (frequency target condition seen by health workers)	Moderate to High	Low	Very Low
Severity of Target Condition(s)			
Life Threatening (likely to cause death if untreated)	Possibly	Infrequently	Rarely
Chronic (likely to cause recurrence, relapse, continued disease if untreated)	Possibly	Infrequently	Rarely
Disabling (likely to cause permanent disability if untreated)	Possibly	Infrequently	Rarely
Restricting (likely to cause loss of working and house-keeping time)	Frequently	Occasionally	Infrequently
Therapeutic Effects			
Drug Action	Prevention of Disease, Cure of Disease, Prevention of Complications	Cure of Disease, Prevention or Treatment of Complications	Cure of Self-Limited Disease, Palliative Treatment of Minor Symptoms, Complications
Therapeutic Efficacy	Proven Effective or Probably Effective	Probably Effective	Possibly Effective, Unknown, or Proven Ineffective
Cost*			
Average Cost of a Single Course-of-Therapy (acute therapy)	Low	Moderate	High
Average Yearly Cost of Therapy (chronic therapy)	Low	Moderate	High

*Cost considerations may be omitted in assigning VEN categories.

Figure VI.B.2.

Examples of Drugs Classified by the VEN System, Sri Lanka

Very Essential - Class 'V' Drugs	Essential - Class 'E' Drugs	Non-Essential - Class 'N' Drugs
Tetracycline Hydrochloride Caps. 250 mg.	Ampicillin Tabs. 125 mg.	Cliquinol Tabs 250 mg.
Aspirin Tabs. 300 mg.	Kaolin Compound Poultice (8 oz.)	Vasaka Compound Syrup
Ampicillin Caps. 250 mg.	Vitamins, A & D soft caps or Tabs.	Calcium Lactate
Prednisolone Tabs. 5 mg.	Potassium Citrate	Aspirin Ethopheptazine Tabs.
Paracetamol Tabs. 500mg. 100's	Licorice Liquid Extract	Mepyromine Malease Cream 2%
Mebendazole Tabs. 100	Ibuprofen Tabs. 200 mg.	Oxyfedrine Tabs. 8 mg.
Phenoxymethyl Penicillin Tabs. 125 mg.	Indomethacin Caps. 25 mg.	Magnesium Trisilicate
Chloroquine Phosphate Tabs. 250 mg.	Campherated Opium Tincture 21	Methyl Nicotinate Compound Cream
	Sodium Salicylate (1 lb.)	Carotonia Seed Powder (Aroben)
	Asorbic Acid Tabs. 100 mg.	

a. Guiding Purchases with the VEN System

Regardless of funding sources, public supply programs frequently find that their calculated requirements exceed available resources. Even where funds are theoretically available, foreign exchange controls may limit drug imports. Under these constraints, drug requests need to be revised, but the process for doing so is frequently haphazard. Purchase quantities may be reduced in proportion to the quantity requested, rather than in proportion to the drug's health impact. Drugs which are unfamiliar to the person making the adjustment may be omitted, despite their medical importance. And orders for full quantities of items routinely obtained from a certain supplier may be maintained, if that supplier has inside contacts with the procurement office.

The VEN system helps to minimize these and other distortions in the drug procurement process, and thus maximize the health impact of available funds, by establishing procurement priorities in advance. Under this system, drugs are assigned VEN categories when they are placed on the drug list or national formulary (see Chapter II.A.). Then, when funding is low or demand is high, the steps below can be followed:

(1) Explore all possibilities for supplemental funding;

(2) Critically review and, where reasonable, adjust drug requirements for all categories;

(3) Wherever possible use safety stocks to fill demand (provided this is a temporary situation and these stocks can be replaced);

(4) Begin by arranging for procurement of "V" items only, then "E" items (setting on-the-spot priorities among these items, if necessary), and finally, if unallocated funds remain, arrange for procurement of "N" items.

This system allows adjustments in drug purchases to be made quickly and easily. Once the VEN categories have been decided by experienced medical personnel, the adjustments can be made by non-medical procurement staff, thus reducing the involvement of medical staff in day-to-day procurement decisions. When correctly applied, the VEN system should result in the most favorable health impact possible with available funds.

Under less extreme circumstances, a system of priorities is valuable in setting policies for safety stocks.

b. Setting Safety Stock Levels with the VEN System

The discussion of holding costs in Chapter IV.B. made it clear that inventory is expensive. An average inventory of U.S.$1,000,000 will cost from $200,000 to as much as $500,000 per year simply to maintain! In light of this expense, it is not reasonable to expect that large safety stocks can be kept for all items.

Since the likelihood of a stockout is directly related to the amount of safety stock kept in inventory, it is paramount that sufficient stocks be kept for life-saving and other critical drugs.

In Sri Lanka, for example, a safety stock of three months' usage is provided for class "V" items, and only one month's usage for class "E" items. To establish similar gradations in an already existing system, a program may gradually allow safety stocks of non-essential drugs to dwindle to low levels, through consumption, and with these savings build up the safety stocks of vital drugs. Thus, the likelihood of shortages of vital drugs can be reduced to almost zero.

c. Other Applications of the VEN System

Once drugs have been classified according to their potential health impact, the classification system can be used for other supply and management purposes. In drug sales programs, for example, the pricing structure can be based to some extent on VEN categories. Drugs judged to be of vital significance, including vaccines and anti-tuberculosis medications, could be distributed at cost or even without charge. Popular non-essential drugs, such as syrups for the common cold and vitamins for people without deficiencies, would be priced considerably above cost. This strategy is considered in detail in Chapter III.E.

Another use of the VEN system is in assigning staff to order-monitoring and stock record activities. Orders for class "V" drugs should be monitored particularly closely, since stockouts of these drugs could be devastating and require costly emergency shipments. It is also important that the stock records for class "V" and "E" drugs be maintained accurately and up-to-date. If inventory control clerks vary in competence, it many prove advantageous to assign the more reliable clerks to the "V" and "E" items.

3. ABC VALUE ANALYSIS

It is a well-known observation in inventory management that most of the value of annual consumption is accounted for by a relatively small number of items. It is useful to carry this observation further by categorizing the items in an inventory into three classes according to the value of their annual usage (unit cost multiplied by the number of units consumed annually). Class A items have the highest annual usage, with 10 to 20 percent of the items usually accounting for 70 to 80 percent of the funds spent. Conversely, class C items account for 60 to 80 percent of the items and only 5 to 25 percent of the value of annual consumption. The cutoff points between class A, B, and C items are flexible and vary with the types of items under consideration and their consumption patterns.

Identification of the relatively small number of items which account for the majority of the funds spent in a supply system has implications for procurement, inventory control, staff utilization, and other supply activities.

a. Performing an ABC Value Analysis

To classify items, the annual dollar usage of each item is calculated by multiplying its unit cost by the number of units consumed each year. The items are then arranged in descending order by the annual dollar usage. The cumulative dollar usage for these items is plotted against the cumulative percent of items. The process is described step by step in Figure VI.B.3.

The example in Figure VI.B.3. is based on a product range of only 20 items and the ABC curve which results is not typical. Figure VI.B.4. provides the summary information and curve for a more typical ABC analysis performed using estimated consumption data for two large public health programs, one in South America and one in Asia.

ABC analysis is possible with any size inventory. It is easily done, even by hand, up to several hundred items, but with larger inventories, computer facilities greatly expedite the process. Computer programs for ABC analysis are readily available.

It is useful to repeat the ABC analysis at least every two years to reflect significant changes in either consumption patterns or relative unit prices of drug items.

Selecting cutoff points between the A, B, and C items may be a source of confusion. There are no specific rules or formulas to follow, but the cutoffs should be made wherever they seem most appropriate. In practice, the division among the groups will depend in part on how results of the analysis are being used. This is the subject of the following sections.

b. Using ABC Analysis to Guide Procurement Patterns

One of the most important inventory control parameters, in terms of the cost and workload involved in procurement, is the order quantity. As indicated

Figure VI.B.3.

How to Perform an ABC Value Analysis

Classification of the items in a drug inventory into ABC categories requires that one know the unit cost of each item (the most recent C.I.F. cost or another standard cost is appropriate) and the annual consumption of each item. To carry out the classification, the following steps should be performed in order:

(1) Multiply the latest unit price by the current annual consumption forecast for that drug to obtain the annual usage figure in dollars. If a recent price is not available, it may be necessary to use the last C.I.F. price with a suitable correction to reflect expected changes in price.

(2) Enter these values of annual usage for each drug in column two of the table, arranging the drugs in descending order of dollar value.

(3) Obtain the cumulative dollar figures for this set of annual requirements and list them in column 3.

(4) These cumulative usage figures should then be expressed as a percentage of the total value of annual requirements of all drugs. These percentages are listed in column 4 and serve as the vertical axis of the ABC Curve given below.

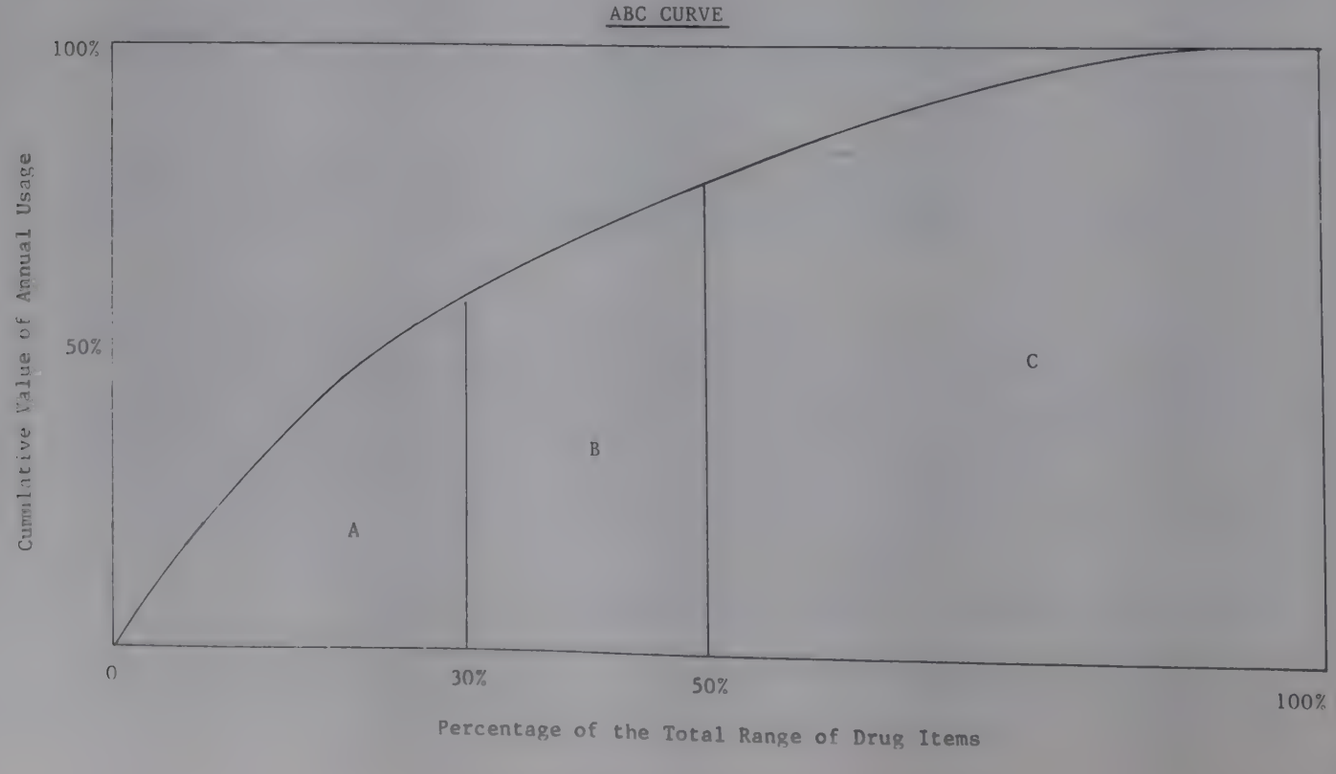
(5) The cumulative percentage of the total number of drugs in the list should be calculated in the same order. These values are listed in column 5 and serve as the horizonal axis of the ABC Curve.

NAME OF DRUG (1)	U.S.$ VALUE OF ANNUAL USAGE (2)	CUMULATIVE U.S.$ VALUE OF ANNUAL USAGE (3)	CUMULATIVE U.S.$ VALUE AS % OF TOTAL (4)	CUMULATIVE NUMBER OF DRUGS AS % OF TOTAL (5)
A	56,522	56,522	12	5
B	53,873	110,395	24	10
C	43,305	153,700	34	15
D	36,975	190,675	42	20
E	35,037	225,712	50	25
F	34,266	259,978	58	30
G	23,521	283,499	63	35
H	23,120	306,619	68	40
I	20,065	326,684	73	45
J	18,758	345,442	77	50
K	18,612	364,054	81	55
L	17,177	381,231	85	60
M	15,716	396,947	88	65
N	9,225	406,172	90	70
O	8,798	414,970	92	75
P	8,297	423,267	94	80
Q	7,204	430,471	96	85
R	6,475	436,946	97	90
S	6,071	443,017	99	95
T	4,415	447,432	100	100

CLASS	RANGE OF ANNUAL CONSUMPTION	% OF TOTAL REQUIREMENTS	% OF TOTAL RANGE OF DRUGS
A	Above U.S.$36,975	42	20
B	Above $18,758 but below $36,975	35	30
C	Below $18,758	23	50

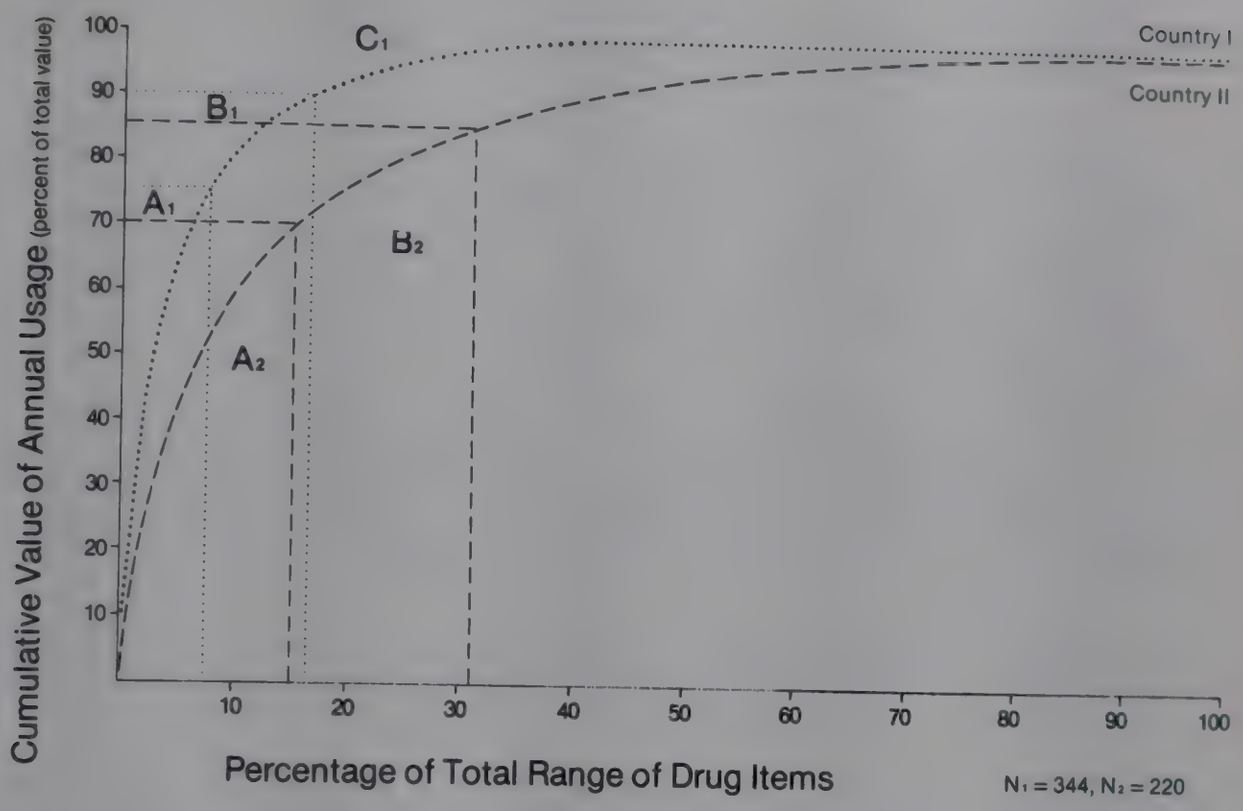
(6) Plot horizontal (column 5) and vertical (column 4) coordinates for each drug to obtain the ABC Curve as given below.

(7) Finally, pick suitable boundaries for A, B, and C class drugs depending on the shape of the curve obtained.



gure VI.B.4.

ypical ABC Analysis for Two Drug Supply Programs



ABC INVENTORY ANALYSIS OF DRUG LISTS, COUNTRY I AND COUNTRY II

UG LIST CHARACTERISTIC	COUNTRY I ABC Category: A	B	C	TOTAL	COUNTRY II ABC Category: A	B	C	TOTAL
mber of Items	25	34	285	344	34	35	151	220
rcent of All Items	7.3	9.9	82.8	100.0	15.5	15.9	68.6	100.0
lue of Annual nsumption (US $)	$11,151,270	$2,197,600	$1,438,274	$14,787,144	$6,401,593	$1,415,641	$1,401,088	$9,218,322
rcent of Total Annual nsumption	75.4	14.9	9.7	100.0	69.4	15.4	15.2	100.0
mber of Units of Stock	275,844,000	97,990,000	148,678,725	522,512,725	1103,858,000	70,511,250	89,063,088	263,432,330
n Number of Units per m	11,033,760	2,882,058	521,680	1,518,932	33,054,647	2,014,607	589,822	1,197,420

in Chapter IV.B., the order quantity influences supply activities in at least four ways:

(1) The order quantity is a major determinant of the average level of stock held over a given period of time. Higher order quantities raise average inventory levels, thus increasing stock holding costs.

(2) The size of the order quantity also determines the frequency of reordering, which in turn affects the workloads of the procurement, import, and medical store staff. The amount of work involved in processing an order by any one of these departments is usually independent of the size of the order. Thus, when order quantities are small, orders are more frequent, and the workloads of all these units increase.

(3) The frequency of ordering also determines how often the on-hand stocks reach low levels before the arrival of new shipments. When the frequency of ordering is increased the probability of being out of stock also increases, unless safety stocks are increased as well.

(4) Larger order quantities tend to result in more favorable bulk prices. However, after a certain point, the effect of increasing order sizes may be small.

In establishing order quantities the objective should be to minimize the number of orders per year, obtain favorable bulk rates wherever possible, and at the same time minimize the average value of the inventory. These seemingly contradictory objectives can be simultaneously realized, in part, through an ABC value analysis.

Because of the high annual usage of class A items, it is advantageous to reduce their inventory by purchasing smaller quantities more frequently. At the same time, the values of class A items are such that bulk discounts can still be anticipated; and the number of class A items is usually small enough that more frequent ordering has a limited impact on the workload of the procurement section. Changing the order quantity from 12 months' to 6 months' usage reduces the inventory by almost one-half, but -- for these relatively few items -- does not greatly increase the workload of the purchasing and import staff.

For example, using the information for Country I in Figure VI.B.4., it is estimated that the average inventory for the country could be reduced by 20 percent, and the number of orders increased by only 10 percent, simply by purchasing class A items twice a year, rather than purchasing all items once a year.

Various combinations of 4, 6, and 12 month order intervals (and corresponding order quantities) can be imagined (Figure VI.B.5.). The main point is that by setting order quantities according to ABC categories, average inventories can be reduced by 20 to 50 percent over single annual purchasing schemes, with a relatively small impact on the workload of the procurement staff and, in many cases, with a small impact on bulk price advantages.

Figure VI.B.5.

Hypothetical Procurement Patterns Based on ABC Analysis

Procurement Pattern	ABC Category	Order (Delivery) Quantity in Months of Consumption	Orders (Deliveries) Per Year	Total Number of Individual Orders (Deliveries) Per Year	
				Country I	Country II
Pattern A				334	220
	A	12	1		
	B	12	1		
	C	12	1		
Pattern B				369	254
	A	6	2		
	B	12	1		
	C	12	1		
Pattern C				403	289
	A	6	2		
	B	6	2		
	C	12	1		
Pattern D				668	440
	A	6	2		
	B	6	2		
	C	6	2		
Pattern E				428	323
	A	4	3		
	B	6	2		
	C	12	1		
Pattern F				1032	660
	A	4	3		
	B	4	3		
	C	4	3		

It is important to recognize that order quantities cannot be based entirely on financial considerations. Other important factors to consider are shelf-life, the likelihood that the demand for a drug will change significantly, the availability of storage space, and the capacity of the different functional units to handle various workloads. ABC analysis provides a piece -- albeit a rather important piece -- of the information needed for management to set optimal order quantities.

c. ABC Analysis and Delivery Schedules

For large drug consignments, buyers frequently have the option of obtaining divided deliveries at little or no additional cost. This option may be part of the original contract conditions set by the buyer when tenders are announced. Where divided deliveries are possible, the pattern for these deliveries can be established using ABC categories in exactly the same manner that they are used for determining order quantities.

For example, if drug contracts are negotiated annually, class A drugs could be shipped to the government two or three times a year. The effect of this would be to reduce inventories of class A items by one-half to one-third. Again, a more elaborate pattern of divided deliveries, similar to the procurement patterns in Figure VI.B.5., can be imagined. The savings from such an approach can be considerable, provided late deliveries do not increase in frequency.

d. Using ABC Analysis to Seek Lower Prices

Since class A items are few in number, it is possible to devote special attention to locating the least expensive suppliers of them; and the value of the A items is such that a small price break by one supplier can have a noticeable impact on total drug expenditures. If drug quality becomes an issue in attempts to reduce expenditures, it may be worth the expense of having suspect drugs analyzed. Routine analysis for all drugs may prove too costly, but for category A items and many category B items such analysis may prove useful in convincing health officials that a less expensive product is acceptable. The cost of the drug analysis, then, would be more than offset by the savings in the purchase price.

Category A and B items can also be reviewed to determine whether less expensive alternative drugs or dosage forms are available.

e. Assignment of Staff

One of the biggest problems in many supply programs is the lack of trained and qualified staff to operate the system. In such instances, it may be useful to assign work such as managing the inventory records, initiating orders, monitoring order status, and even port-clearing of class A drugs to the more experienced staff. Since this small range of products represents a very large proportion of the total value, careful staff assignments would certainly help to avoid costly errors and maintain proper control.

f. Stock-Taking

One of the routine functions performed by stores' personnel is that of stock-taking, in which a physical count of drugs is taken and checked against the balance on bin cards and in inventory control records. This process can be rather time consuming where there is a very large range of different drugs maintained in stock. When time is limited, checking of class A drugs more frequently and carefully provides an easy and effective method of checking a very large percentage of the total dollar value of the stock on hand.

4. LEAD TIME ANALYSIS

Lead time is defined as the interval between the making of a decision to order stock, and the issue of a Receiving Report by the medical stores, indicating that the drug is available for distribution. Proper estimation of the lead time period is one of the most important functions in any supply system. Failure to estimate it accurately almost invariably leads to frequent stockouts.

Because a large proportion of drugs required by developing countries are imported, the lead times are long, and also highly variable. A sample of lead times for drugs imported by the State Pharmaceuticals Corporation of Sri

Lanka is illustrated in Country Study VI.B.1., which shows the variability that is observed in practice.

Country Study VI.B.1. also illustrates one of the common pitfalls of public supply programs and one of the causes for frequent shortages: the procurement department, in this case, was basing its projections on an expected lead time of 180 days (6 months), while the average lead time, in actuality, was over nine months, and for 3 of the 22 suppliers studied, the lead time was twelve months or more. Such gross underestimates of lead time should be avoided by systematic use of supplier files, which record the delivery performance of each supplier (see Chapter III.C.), and other elements in the information system.

In determining expected lead times by analyzing past data, it is necessary to first find out what purchasing method was used in each case. Average lead time values will usually change considerably with different purchasing methods. For example, the lead times for drugs purchased on open tender are considerably longer than those for drugs purchased directly.

5. REDUCING WASTE FROM EXPIRED PRODUCTS

Because of the length of the supply pipeline and the storage and transportation conditions frequently encountered along this pipeline, the potential for spoilage and expiration of pharmaceuticals is substantial. Efforts to reduce waste in these areas should begin at drug selection and continue through end-use dispensing at a health facility or by a village health worker.

It was noted earlier, in Chapter III.D., that pharmaceuticals are dynamic products with limited shelf-lives, as determined by their formulation, packaging, shipping conditions, and storage conditions, among other factors (see Figure III.D.1.). It is not uncommon for drugs to reach the end of their shelf-life -- or their expiration date -- before they are used, for a variety of reasons. Policies with regard to the use of expired products vary from program to program and pharmacist to pharmacist. Some of the technical aspects of this problem are presented in Chapter III.D. But the objective of the supply system should be to avoid accumulating stock with short shelf-lives and to handle short-dated products as efficiently as possible to avoid their expiring before being used. The remainder of this section focuses on these objectives.

a. Avoiding Short Shelf-Life Stock

Numerous practices and supply management techniques have been used to avoid the accumulation of short-dated products in the drug inventory. The most easily applied practices are described briefly below.

(1) Drug Selection -- Shelf-lives are determined more by the drug category (vaccine versus tablet, for example) than by the specific drug product (penicillin versus ampicillin, for example). Nevertheless, among

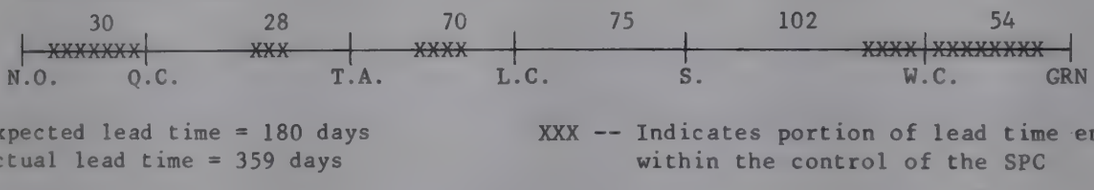
Country Study VI.B.1.

Lead Time Analysis in a National Pharmaceutical Corporation

At the inception of the State Pharmaceuticals Corporation (SPC) of Sri Lanka the lead times for importing drugs were observed to be quite long and variable. However, the SPC assumed a much lower value for the expected lead time period for the purpose of making decisions regarding when to order. The result was frequent stockouts, including stockouts of critical life-saving drugs. To overcome this problem, the SPC often had to airfreight drugs and resort to panic buying, which proved to be very costly. Hence, an analysis of lead times was carried out to identify the main causes of delay, and to see what corrective action would need to be taken to improve performance.

The analysis was carried out by dividing the total lead time period for an order into six components. On studying these components it was possible to identify particular areas which were subjected to long delays. In the example illustrated below, the values indicated on the figure are the times taken in days for each component of the lead time to be completed.

N.O. - Need to Order
Q.C. - Quotations Called
T.A. - Tender Approved
L.C. - Letter of Credit Established
S. - Shipped
W.C. - Wharf Clearance
GRN - Goods Received Note issued by stores



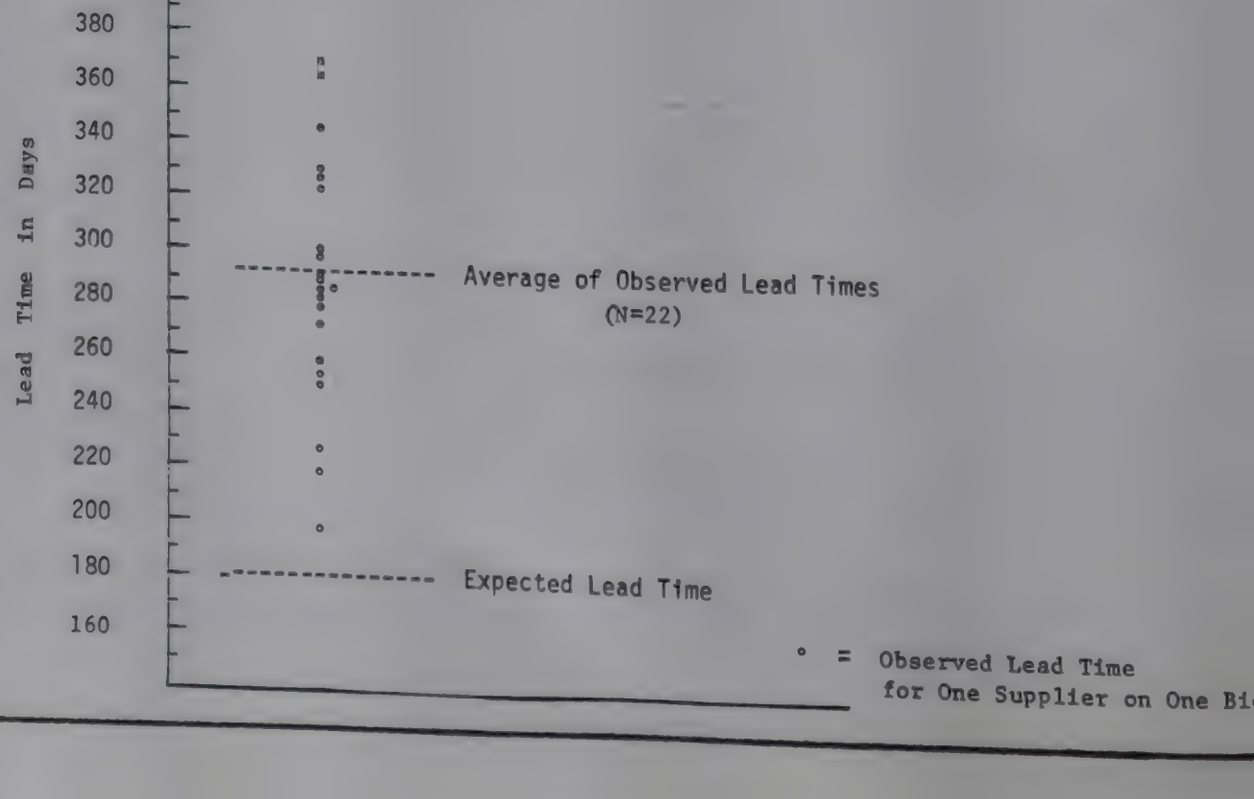
Expected lead time = 180 days
Actual lead time = 359 days

XXX -- Indicates portion of lead time entirely within the control of the SPC

It was clear from this analysis that as much as 50% of the total lead time period was within the control of the organization. Hence, departments such as wharf, purchasing, and inventory control were completely reorganized to improve efficiency, and new systems and procedures were introduced wherever necessary to improve planning and control.

As a result of these changes, the lead times (on an average) were reduced by as much as two months or more, and the lead time variability was also substantially reduced. Hence, it became possible to operate the inventory control system on the basis of the nine month expected lead time period. Benefits to the State Pharmaceuticals Corporation as a result included:

1. Fewer stockouts, less panic buying, and less airfreight for essential drugs.
2. Substantial reduction in buffer stocks.



alternative drugs there is sometimes variation in shelf-lives and this should be considered when making initial drug selections.

(2) Order Quantities -- In some systems, order quantities are determined from inventory records by stock control clerks who have little pharmaceutical training. These quantities should be reviewed by a pharmacist, physician, or other health professional to adjust order quantities and, if necessary, arrange for divided deliveries for those products with short shelf-lives.

(3) Contract Terms and Inspection of Shipments -- In some programs drug supply contracts specify that, with a few exceptions, drugs should arrive in the country with at least a two year shelf-life (see Chapter III.B.). Such contracts place an obligation on the supplier; but, to be effective, they must be enforced. On receipt of drugs at the port or in the medical warehouse, inspectors should check expiration dates. Demand for drugs does not usually permit the return of an entire shipment, but suppliers who send short-dated products can be avoided in the future. Any losses from expired products can be deducted from the supplier's security deposit (if there is one); or part of the shipment can be returned for credit.

(4) Stock Rotation -- Anyone handling drug supplies, from chief storekeeper to village health worker, should be indoctrinated in the principle of "first in/first out" stock management. The earliest stock received should be issued first and the most recent stock should be put at the back of the shelf to be issued only after earlier stock has been used. Drug stocks tend to get dusty after several weeks of storage but this problem should be solved by dusting -- not by leaving the dusty stock at the back of the shelf and using only the new stock.

Supervisory visits to storage facilities should always include a review of stock rotation practices and a look at the "dust line" on the supply shelves.

(5) Monitoring Shelf-Lives with Stock Records -- Stock record cards can be used to monitor shelf-life, either by including a special column for shelf-life on the card or by using a separate card for each shipment with a different shelf-life. The inventory control clerks or storekeeper responsible for reviewing the stock control cards to determine order quantities can then check to determine whether stocks are approaching their expiration dates. If so, one of the procedures described in the next section can be followed.

(6) Bin Cards -- In place of, or in addition to, stock records, bin cards can be used to monitor expiration dates. Bin cards for products with short expiration dates should be pink or red, rather than tan or white. This alerts storekeepers, dispensers, or pharmacists to check these products regularly to assure that the stock is being rotated properly and to monitor their consumption more carefully.

(7) Staff Diligence -- Most of the above procedures require that the staff members involved be conscientious in stock monitoring activities.

Supervising these activities and impressing supply staff with the importance of preventing product expiration are vital. At least one country has instituted fines for dispensers who neglect to inform their supervisors that drugs are nearing their expiration date. While this approach cannot be advocated as a sure solution to preventing stock expiration, it does underline the importance attached to reducing such losses.

b. Handling Short Shelf-Life Drugs

When the above techniques have failed to keep drugs from approaching their expiration dates, several actions are possible.

(1) Notification of Impending Expiration -- Storekeepers and other individuals responsible for drug stocks at each supply point should maintain a list of drugs nearing their expiration dates (e.g., within three to six months of expiration) and should notify the supply source at the next level up (district hospital, regional store, or central store) if it does not appear that the stock will be consumed before expiration.

Impending expiration of products should be apparent from consumption data, as the following example illustrates:

- There are 1000 units on hand of a drug with a six month shelf-life.
- The estimated average monthly consumption for this drug is 100 units.
- Therefore, the present on-hand stock would last for approximately 10 months.
- Consequently, the expected number of units that would get outdated is approximately 400 units.

These 400 units, then, should be redistributed to other facilities.

(2) Redistribution -- In addition to having a system for notification of impending expirations, the supply system needs a system for redistributing short-dated products. A common fear of health workers at peripheral facilities is that if they return short-dated stock, they will receive no replacement stock. This problem has been alleviated in one South American program where hospital pharmacists in each health area gather periodically to compare lists of overstocked, understocked, and short-dated products. Sometimes they will actually carry the stock to the meetings. Similar systems exist in at least one Southeast Asian country and elsewhere.

Redistribution of short-dated products to facilities experiencing a greater demand for specific products can be structured using a form something like a drug supply requisition.

(3) Return to Supplier for Analysis -- One major supply program reports that samples of drugs approaching their expiration date are sometimes sent to the supplier for analysis. On the basis of the supplier's data regarding the drug's deterioration curve, some estimate can be made of whether the drug can still be used and, if so, for how long. Since experienced manufacturers often formulate their drugs with a margin of safety, drugs which have been stored properly will frequently prove to retain their potency longer than originally indicated on the label. Obviously, this strategy requires good supplier relations.

(4) Exchange of Drugs -- Some suppliers will allow for an exchange of drugs which are approaching their expiration dates for drugs with longer shelf-lives, provided there is enough shelf-life remaining for the supplier to sell the drug in a rapidly moving market. This practice is most feasible where there are reliable local agents and a well-established local commercial market for the drugs.

6. PIPELINE ANALYSIS

The concept of the supply pipeline was introduced in Chapter II.B. and considered again from a financial viewpoint in Chapter III.E. A drug distribution system resembles a pipeline with several storage tanks along its length. The cost of delivering drug supplies through the pipeline is determined largely by the number of storage points in the system's hierarchy, the delivery interval between each of the levels in the system, the range of drugs supplied at each level, and the volume of drugs stored at each point.

In addition to the cost of the drugs which are ultimately dispensed (see sample calculation in Country Study III.E.5.), the structure of the supply network will influence other costs arising from:

- transportation from one level to facilities at lower levels,
- supply handling,
- administration and record-keeping,
- storage and security, and
- safety stock.

Logistics experts have for years attempted to find simple ways of determining the optimal arrangement for a distribution network. Unfortunately, no easy solution exists. The examples given in Figure IV.D.2. in Chapter IV.D. illustrate the impact which changes in the distribution network can have on average drug inventories.

Although a single optimum may not exist, a systematic approach to pipeline analysis may lead to the most effective, efficient system possible under existing constraints. This approach is similar to the planning strategy described in Chapter I.C. Any distribution system developed must fit into

the overall pharmaceutical logistics plan. The basic steps are as follows:

(1) Consider current and potential personnel, storage, and transportation resources and anticipated drug requirements at all clinical facilities served by the program. Based on this consideration, diagram all (or at least three) possible arrangements of storage points and clinical facilities (similar to Figure IV.D.2.) in a distribution network.

(2) Outline several feasible delivery schedules for each of the potential distribution networks identified in the previous step. Add to this estimates of the safety stock and working inventory required for each of the delivery schedules.

(3) Estimate the development and startup costs for each of the systems outlined. The form in Figure I.C.7. in Chapter I.C. might be used for these estimates.

(4) Choose the system with the lowest estimated cost as the optimum toward which program development should be aimed.

In estimating drug supplies for each level of the system, it may be useful to apply the level-of-use categories described in Chapter II.A. These categories would indicate which types of drugs would be found at each level and are therefore useful in estimating stock levels.

Once a distribution network has been established, it may be difficult to redesign the system. Nevertheless, it may prove rewarding to review it periodically (every two or three years, for example). The network should be diagrammed, with stock points and distribution points included, and inventory levels and delivery schedules estimated. Based on this diagram, alternative distribution patterns can be considered and their costs estimated. Incremental improvements in the form of reduced safety stocks, more reliable supply, and more efficient delivery schedules may result.

SUMMARY

Cost reducing strategies are aimed at increasing the effectiveness and efficiency of drug supply.

Effectiveness is the degree to which the system provides the required services. The stockout rate is, in many ways, the converse of effectiveness. Efficiency is the extent to which effectiveness is reached while minimizing costs. Several management techniques are available to help improve effectiveness and efficiency.

The VEN System is a system of categorizing drugs by their health impact. It can be useful in setting purchasing priorities, in determining safety stock levels, and in directing staff activities. Categories are:

V -- VITAL drugs which are potentially life-saving, which have significant withdrawal side-effects such that regular supply is mandatory, or which are included in basic drug lists (e.g., vaccines);

E -- ESSENTIAL drugs which are effective against less severe, but nevertheless significant forms of illness;

N -- NON-ESSENTIAL or normal usage drugs for minor or self-limited illnesses, drugs which are of questionable efficacy, and drugs which have a high cost for a marginal therapeutic advantage.

ABC Value Analysis divides drugs by their annual usage (unit cost times annual consumption) into Class A items (the 10 to 20 % of the items which account for 70 to 80 % of the funds spent), Class B items (with intermediate usage rates), and Class C items (the vast majority of items which account for less than 25 % of the funds spent). ABC analysis can be used to:

- Reduce inventory levels and costs by arranging for more frequent purchase or delivery of smaller quantities of Class A items.
- Seek major cost reductions by concentrating on finding lower prices on Class A items, where savings will be more noticeable.
- Assign Import and Inventory Control staff, to assure that large orders of Class A items are expeditiously handled.

Lead time analysis is a systematic approach to understanding the components of procurement lead times and determining the points at which the lead time can be reduced.

Reducing waste due to expired products can be accomplished with careful attention to drug selection, order quantities, contract terms and inspection of shipments, stock rotation, monitoring of shelf-lives, notification procedures for impending expirations, redistribution mechanisms for short-dated products, and exchange arrangements with suppliers.

Pipeline analysis can help to identify the location of stock in the distribution network and serves as the basis for devising more efficient stock-keeping policies.

CHAPTER VI.B. REFERENCES

Ammer, D.S.: Purchasing and Materials Management for Health Care Institutions. Lexington, MA: D.C. Heath and Co., 1975.

Dias, V.: State Pharmaceuticals Corporation Report No. 1, Introduction of Forecasting and Inventory Control Systems. Colombo, Sri Lanka: National Institute of Management, 1975.

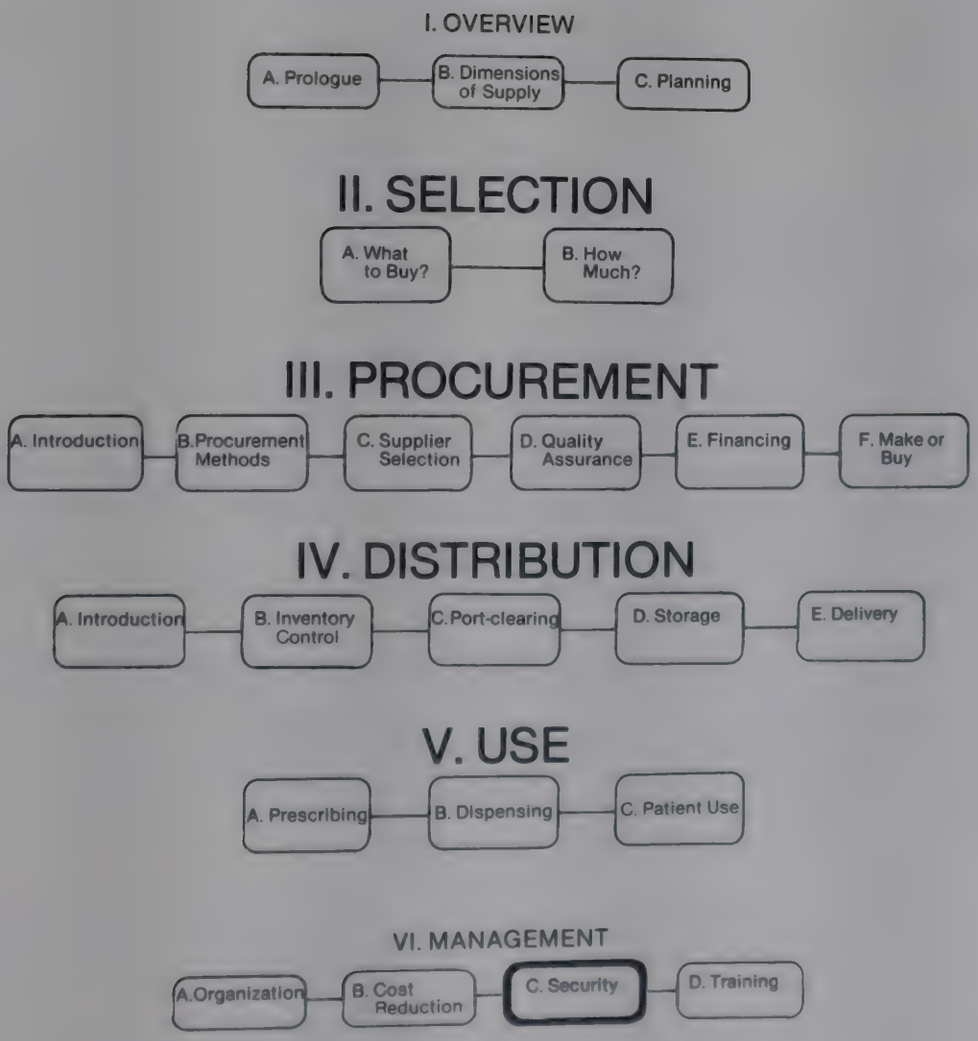
Drug and Therapeutics Bulletin: Storage and Shelf Life of Drugs: When is it Important? Drug and Therapeutics Bulletin, 1977.

Pinkus, C.E. et al.: Optimal Design of Multiactivity Multifacility Systems by Branch and Bound. Operations Research 21: 270-283, 1973.

Quick, J.D.: Applying Management Science in Developing Countries: ABC Analysis to Plan Public Drug Procurement. Socio-Economic Planning Sciences (in press).

Chapter VI.C.

Security System



	Page
1. ANALYSIS OF SECURITY BREACHES	515
Systematic Search for Security Breaches	
2. METHODS FOR PREVENTING SECURITY BREACHES	517
a. Theft	519
Unique Identifiers Theft Prevention Closing the Outlets	
b. Bribery	524
c. Fraud	526
3. THE COST OF SECURITY	527
SUMMARY	528

Security System

Incidents of theft, bribery, and fraud can interfere with the smooth and effective functioning of national drug supply systems. In some countries, these breaches of security are almost non-existent, while in others they can be the single most devastating problem for drug programs, raising costs and threatening the entire effectiveness of the program.

In one central African country, for example, a hospital pharmacist noted that in placing her drug orders she routinely allowed for losses of 80 to 90 percent on certain drugs in order to maintain quantities sufficient for treating hospital patients. In an extremely poor southeast Asian country losses due to theft have been estimated to be in excess of 30 percent of the total drug supply, despite strict drug accounting requirements. The government medical store in an East African country is reported to have placed an order for over U.S.$100,000 worth of pharmaceutical cocaine, which vanished from the wharf upon its arrival.

There are other examples. In a country in Central America, inventory records for the social security system showed stock levels of oral ampicillin, antibiotic eye ointment, and dozens of other products to be enough for 3, 5, 10 and up to 30 years' consumption, because government buyers received special "commissions" for their purchases. Theft of antibiotics for black market sale and treatment of venereal disease occurs on every continent. At the same time, there are many countries throughout the world where losses are minimal, confined to low-volume pilferage for personal and family use.

Whatever the form or extent of the security breach, there are measures that can be used to deal with them. Even in countries where bribery may exist and theft may be coordinated or condoned at high levels, there has been success in reducing these activities when a strong commitment has been made at an even higher level. The circumstances which lead to substantial losses in some countries include a wide range of cultural, political, and economic factors. Nevertheless, if the political will and control exist, these factors can be overcome. Several control measures which have proved effective will be discussed in this chapter.

Improving security involves (1) an analysis of the sources of security breaches, (2) a consideration of the methods for improving security, and (3) an evaluation of the relative costs of security measures, in light of the financial and public health costs of inadequate security.

1. ANALYSIS OF SECURITY BREACHES

Security breaches include theft, bribery, and fraud, and can occur at any and all levels of the drug purchasing and distribution system. These breaches can entail a variety of potential costs to the country:

- unnecessary suffering and sometimes death resulting from drug shortages caused by thefts and expenditures on unnecessary drugs;

- expenditures on unnecessary, or officially unapproved, types or quantities of drugs by purchasing officials seeking illegal "commissio from vendors;

- additional expenditures on necessary drugs to compensate for inadequat supplies resulting from theft and intentional short packing; and

- the need to use more expensive antibiotics as a result of drug resistance developed after frequent improper use of black market antibiotics.

The major types of security breaches are summarized in Figure VI.C.1., showing the levels at which they occur and giving examples of breaches observe in various parts of the world.

The most pervasive problem is that of theft. Stolen drugs find their way to four major outlets:

(1) Export for sale in adjacent countries via legitimate or illegitimate trade routes.

(2) Black market wholesale to local warehouses, pharmacists, or physicians legitimate retail sale.

(3) Black market direct sales to the public through street vendors.

(4) Free distribution to family and friends.

In addition to theft, bribery of purchasing officials and fraud at the level of the suppliers can entail significant costs to some countries.

Systematic Search for Security Breaches

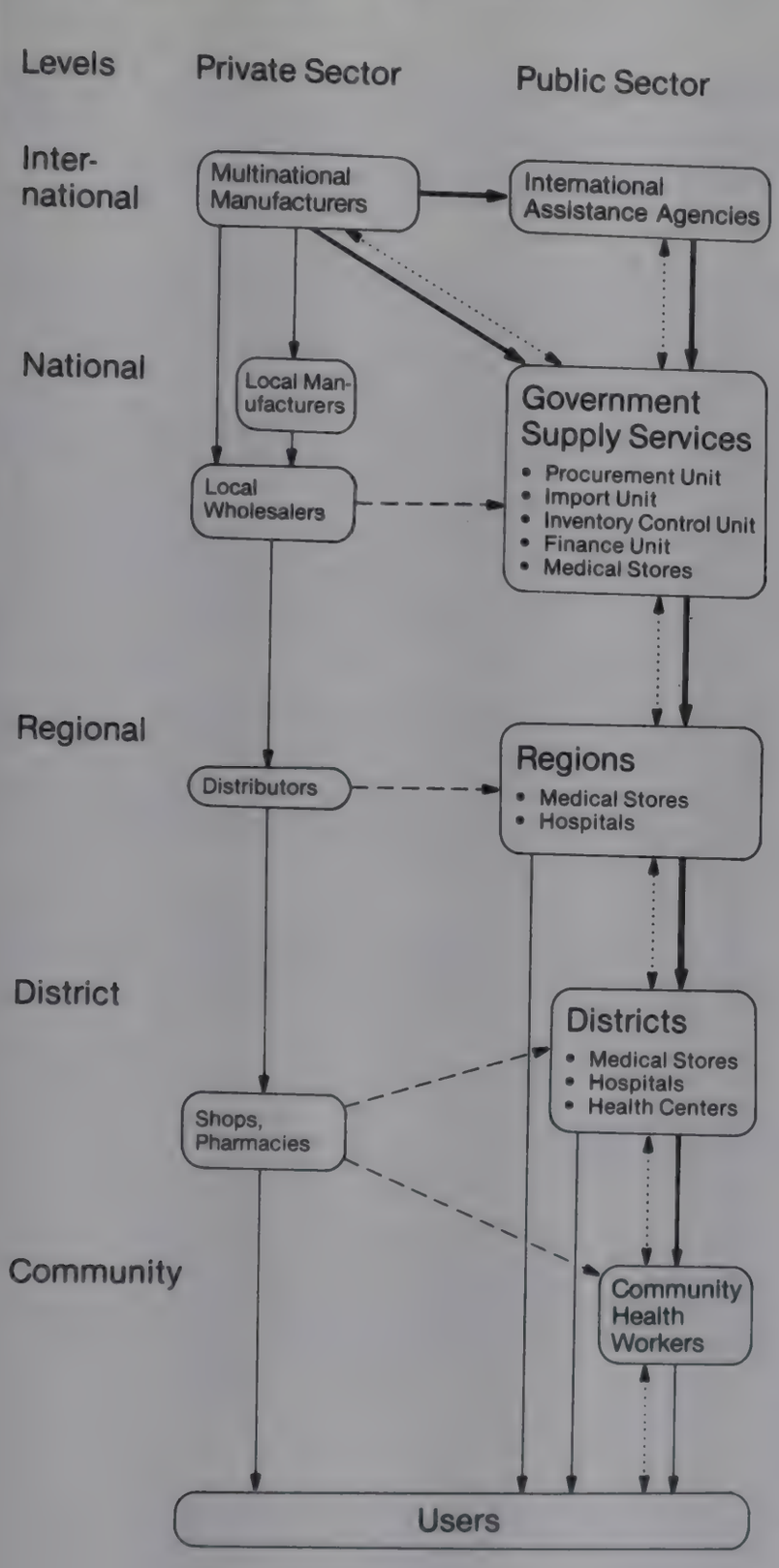
Identification of major security breaches and the levels at which they are most prevalent is the first step to controlling them. There are several methods for uncovering theft, bribery, and fraud.

(1) Informal channels provide the simplest, most accessible means. Major theft and bribery schemes are often known or at least suspected by pharmacists physicians, politicians, and other officials. Large stocks of unissued and unuseable drugs at medical stores, the overnight disappearance of large quantities of drugs, systematic failure of deliveries to reach their final destinations, and frequent shortages at well-supplied facilities are useful indications of the existence of a problem. Simply allowing anonymous, informa channels to surface the problems and then responding vigorously can be quite effective.

(2) Independent stock-takes (physical inventories) and analysis of drug requisitions begins the search for drug losses at the level of procurement an

Figure VI.C.1.

Analysis of Security Breaches



Key

Flow of Drugs

Information Flow

SUPPLIERS
(manufacturers, foreign suppliers, importers)
- Intentional short-packing.
- Intentional omission of expensive active ingredients.
- Shipping of products near their expiration date.
- Dilution and repacking of liquid medications.
- Delivery of incomplete orders and billing for full amounts.

WHARF/AIRPORT
- Off-loading of government shipments directly onto vessels bound for nearby countries.
- Petty theft by port workers.
- Major theft from wharves, customs warehouses, airport fields, etc.

PURCHASING OFFICE
- Acceptance of bribes in return for:
  . purchase of unnecessary types of drugs,
  . purchase of excessively large quantities of drugs,
  . purchase from specific suppliers.
- Intentional over-purchasing to obtain quantities sufficient for systematic diversion into the black market while maintaining legitimate government distribution.

MEDICAL STORES
(central, regional and hospital)
- Major theft through breaking and entering.
- Major systematic theft by employees.
- Acceptance of bribes from suppliers for intentional over-ordering of specific items.
- Intentional under-ordering by government pharmacists or storekeepers, so that shortages will arise, followed by compensatory purchasing from local pharmacists who offer illegal "commissions".

TRANSPORTATION
- Selling of drugs by drivers and at markets along the delivery route.
- Acceptance of payments by drivers for delivering all or part of a shipment to a black market storehouse.
- Trucks hijacked or robbed in transit.

IN-HOSPITAL
- Petty theft by delivery staff, nurses, and doctors for personal and family use.
- Drinking of spirited preparations by delivery staff, who refill bottles with water.
- Systematic diversion of large quantities for black market sale.
- Theft of large quantities by nursing staff for use in their own unofficial private practices.

OUTPATIENT DEPARTMENTS
- Writing of false prescriptions by patients to obtain drugs for resale.
- Visits by patients to multiple clinics to obtain and fill prescriptions for antibiotics, analgesics and other popular resale items.
- Writing of multiple prescriptions by physicians -- to the same person or to false names -- in return for a share of resulting black market sales.

HEALTH CENTERS/VILLAGE HEALTH WORKERS
- Pilfering by government physicians of health center supplies for use in their private practices.
- Popular black market items over-ordered from medical stores and diverted by physicians, nurses, dispensers, or laborers.

central stores. Without warning or without the knowledge of drug supply staff, a stock-take can be performed and results compared with drug receipts and issues.

In a similar manner, stock-takes and audits of existing records can be done at the regional, hospital, and community levels. Sampling of systematically selected facilities will sometimes be sufficient to determine the extent of a problem.

(3) Consumption comparisons using inventory records for each health facili or health district can sometimes be quite revealing. For example, in one Central American country, pilferage of significant quantities of medical supplies, equipment, and food were uncovered by comparing the issues to individual facilities with the actual usage levels. For a specified period of time, issues to the hospitals were recorded, and consumption levels noted in a table by supply category and hospital. A comparison of the utilization patterns and patients served suggested that certain hospitals had suspicious overuse of supplies. The hospitals and departments involved were then more carefully scrutinized. A similar approach, comparing the pattern of drug use by individual drug category and facility, has been helpful in other countries.

(4) Surveying suspected outlets for black market sales is often productive Where government-purchased drugs can be distinguished by type of capsule, batch number, packaging, or some other identifier, a survey of street vendors, pharmacies and physicians' offices has proven to be a useful beginning for tracing the flow of drugs from government sources.

Once it has been determined where the major sources of losses are, method for preventing security breaches can be designed and implemented.

2. METHODS FOR PREVENTING SECURITY BREACHES

A fundamental tool for monitoring security breaches of all forms is a good information and inventory system of the type described in Chapter IV.B. At each level in the flow of drugs (see Figure VI.C.1.) records should exist to indicate how much of each type of drug was received, who received the drugs and verified the amounts, and from whom the drugs were received. Information on drug issues should similarly exist.

Such information provides a historical record and thereby a potential audit trail for the purchase, distribution, and consumption of drugs. The records provide a basis for comparisons as in the analysis of central medical stores mentioned above, and discrepancies that are discovered are likely to provide a starting point for tracing breaches in security. Furthermore, a well-organized inventory system allows purchasing decisions to be based on actual consumption patterns, rather than made ad hoc by individual purchasing officers.

In spite of the obvious advantages of a good information system, it alone may not ensure adequate security. For each type of security breach, other measures are needed.

a. Theft

Two approaches to controlling theft are (1) theft prevention and (2) closing the outlets for stolen goods. In both cases, it is highly advantageous and often essential to be able to distinguish publicly-supplied drugs from commercially-supplied drugs.

Unique Identifiers

A problem in many countries is that an individual caught with drugs believed to be stolen claims that the drugs were purchased. Although the drugs may have been stolen from government stores, it is difficult to prove this without some means of recognizing government drugs. Unique identifiers of the type shown in Figure VI.C.2. can be especially helpful. To establish a system of unique identifiers, a country can require suppliers to:

- Imprint all immediate containers (bottles, boxes, foil packages) and external packing (cartons, crates) with a unique government seal or monogram; or

- Register batch numbers on all immediate containers and external packing and agree not to sell products from the same batch to any other buyer in the country or in adjacent countries; or

- Emboss tablets and print capsules with a unique government monogram.

Systems of unique identifiers have been introduced in many drug programs and there is no single system which is best in all situations. Selection of a specific type of unique identifier should take into account the types and quantities of drugs purchased, the willingness with which suppliers provide labeling services and the expense of doing so, the speed with which deliveries are needed, and the location and extent of drug theft.

(1) Imprinting containers and packaging -- The commonest type of identifier used is the imprinting of immediate containers and external packing with the name or initials of the government program, the seal of the government, or some other symbol. In one South American country, individual foil packets as well as external boxes contain the program title, "Medicamentos Basicos", and all are printed with the same color code.*

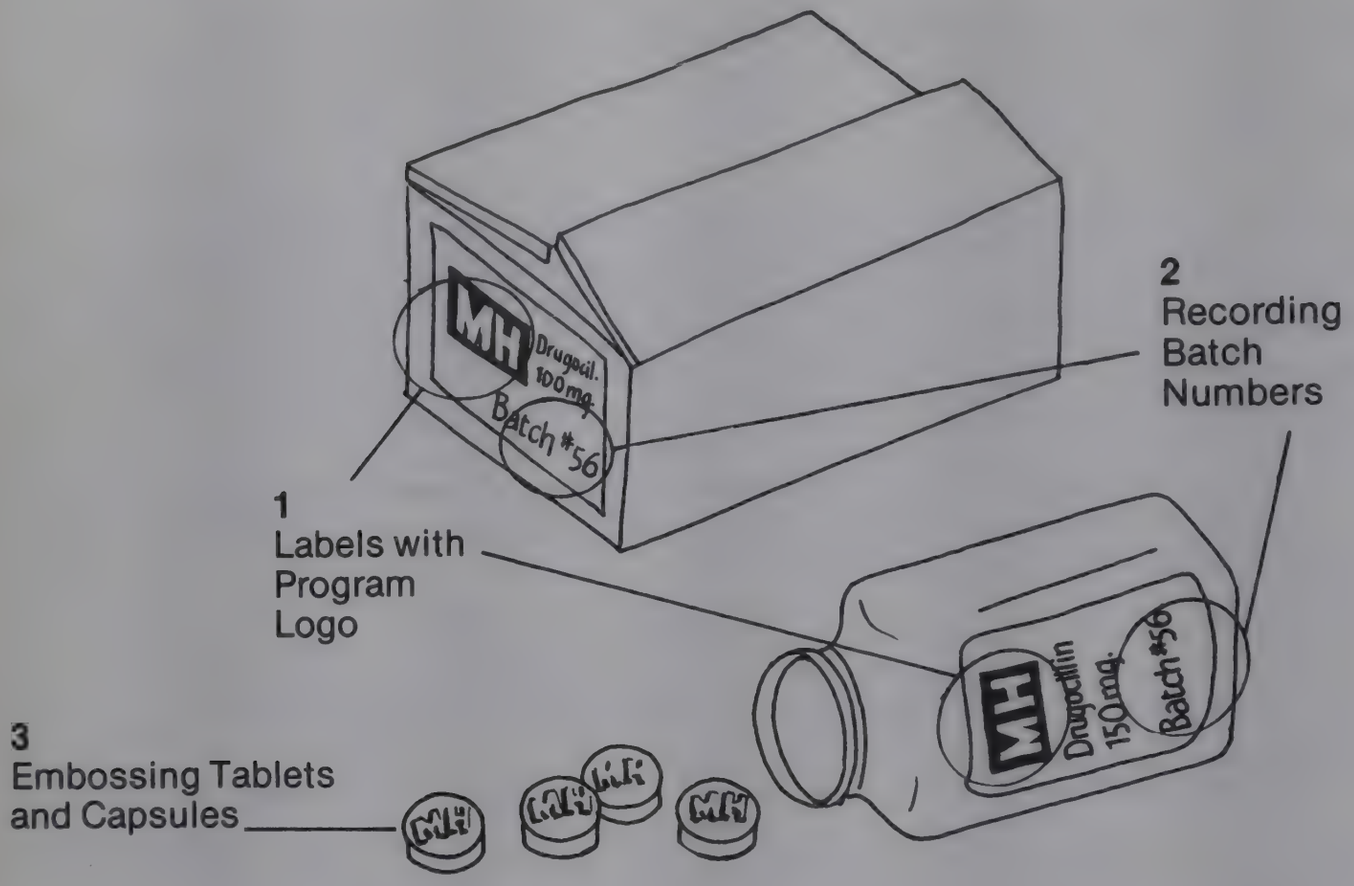
In Sri Lanka, all container labels are required to bear the national seal, which is distributed to all suppliers for their printers to use. In Malaysia, all containers bear the words "Kementerian Kesihatan" -- "Ministry of Health" in the national language.

---

* Unfortunately, medication errors -- some fatal -- have resulted from some combination of the following: (1) a common color scheme which did not differentiate between drugs or drug dosages, (2) small printing on the individual foil packets and ampules which, although necessary to accomodate all the information established in the labeling requirements, was hard to read, and (3) lack of dispensing conscientiousness.

Figure VI. C. 2.

Unique Identifiers: The Means to Recognize Stolen Drugs



The imprinting of containers has been helpful in identifying stolen drugs only when the drugs are kept in their original containers by the thieves. However, when drugs have been purchased in plastic-lined containers of several thousand pills, it is an easy task for thieves to remove the inner lining and thus the identifier. The effect of the imprinting requirement is thereby lost. When the immediate containers are individual foil packets or blister packages, the time and effort of removing the pills from the identifiable containers is greatly increased, and thieves are thereby discouraged.

Container imprinting has the disadvantage of taking extra time in the packing process. Requiring imprinting on all immediate and external containers may delay shipments, increase the price, or completely dissuade some suppliers from bidding on a particular order. A solution used in some countries is to set a minimum order value over which all containers must be imprinted.

(2) Batch number registration -- Imprinting containers may not be complete effective in controlling losses by theft. Thieves at nearly all levels of sophistication become aware of the labeling and can make provisions to repack the drugs. In contrast, the use of batch numbers as unique identifiers is not immediately obvious. By instituting a policy of not allowing suppliers to sell products with the same batch number anywhere else in West Africa, one West African country was able to identify stolen goods and, thereby, to close several major wholesal

Country Study VI.C.1.

Tablet and Capsule Embossing in Southeast Asia

In one successful government pharmaceutical supply program, contracts made by the Government Medical Stores with outside suppliers specify that tablets and capsules in quantities over 500,000 units must be embossed with the Ministry of Health initials. In addition, all tablets produced by the government pharmaceutical plant are embossed with the Ministry's initials.

Theft for personal use and black market sales of attractive items such as diazepam, acetaminophen, antibiotics (used extensively for venereal disease), and other drugs is a steady, if small-scale, drain on major hospitals' drug supplies. Individual ampicillin and tetracycline tablets, which cost the government less than U.S.$.04 are sold for $0.50 to $1.00 each on the black market.

The embossing of tablets has not stopped this level of activity, but it has had a substantial effect on large-volume theft and subsequent sale to commercial pharmacies and to physicians. In 1975, losses due to theft during the wharf clearing and delivery process amounted to 5 to 10 percent. A thorough investigation of pharmacies and doctors' offices in the capital city uncovered several places which dealt in stolen drugs. The prosecutions that followed brought a rapid reduction in thefts. Without the embossing on the tablets and capsules, it would have been difficult, if not impossible, to prove that the drugs had come from government stores.

Although the contracts specify that embossing should be done for both tablets and capsules, it is not always required for capsules. The reason is one of cost and delivery time. For tablets, the embossing is done by the same punch which produces the tablet; no additional step is required in the manufacturing process. The only significant cost and delay is during the first order to a specific supplier. Once the supplier has obtained the necessary punches, he simply sets them in place instead of his own when he begins the production run for the government order.

For capsules, the requirement that they be embossed usually adds an extra step to the manufacturing process, since a punch step is not otherwise required. If the manufacturer normally prints his logo or an identifying number on the capsule, then the requirement that the Ministry of Health initials also be printed does not add to the number of manufacturing steps.

If it appears that requiring embossing will significantly affect cost for a specific item, the government may waive the embossing requirement. Also, when large orders are needed quickly, the requirement can be waived to allow the supplier to fill the order from stock on hand. To speed delivery, the Government Medical Stores will frequently request a divided order, specifying that the first shipment may be unembossed, but that subsequent shipments on the order must be embossed.

and retail outlets for stolen government drugs, and to reclaim thousands of dollars worth of stolen drugs.

Since the unique batch number requirement affects distribution without adding any manufacturing steps, it is less likely to influence the cost or delivery time. However, this label, like the government seal or logo, can be removed or the container discarded by thieves who are aware of the system. Use of batch numbers as unique identifiers does require a special clause in the drug contract and it requires clerical staff to carefully register the batch numbers as soon as a drug shipment arrives.

(3) Tablet embossing and capsule imprinting -- The most successful type of identifier appears to be embossing individual tablets and imprinting individual capsules with the drug program's initials or seal. Country Study VI.C.1. describes how this practice has been implemented in a Southeast Asian country. Embossing and imprinting is accomplished most easily when drugs are produced locally or by the government. When they are imported, the potential problems of delayed shipments

and significant increases in the unit price can be somewhat alleviated by flexibility in enforcing the requirement (e.g., not enforcing it for small-volume items).

Theft Prevention

There are as many potential points for theft as there are steps in the flow of drugs from port to patient. While it is probably not possible or even worthwhile to design a system which prevents theft at every potential point, it is possible to implement measures which attack it at the major sources.

Figure VI.C.3. provides a sampling of theft control techniques which are being used in various parts of the developing world. Unfortunately, the comparative effectiveness of the various techniques is not known. Furthermore, it is likely that the effectiveness of different techniques will vary from country to country as the commitment of the responsible individuals varies and as the political, cultural, and economic conditions vary.

A basic principle in theft control is to provide secure storage places with limited access at all points in the distribution system. Country Study VI.C.2. describes the procedures established for the safekeeping of drugs at the central warehouse in Afghanistan.

A second principle is to actively use the information system to trace the point of theft when large losses are suspected. A well-kept inventory system is of no value unless periodic independent physical stock-takes are made and receipts and issues reconciled with the physical stock. Country Study VI.C.3. describes the drug accounting procedures in one Asian country.

Closing the Outlets

When the major outlet for stolen goods is black market sale within the country, the incentive to steal is obviously reduced greatly by closing black market outlets. This is most feasible when the outlets can be easily identified as private wholesalers, pharmacies, and physicians. Systematic investigation of these suspected outlets is often more fruitful if government drugs carry unique identifiers.

One difficulty in this type of enforcement is that police are often unwilling or unable to devote time to such activities. To solve this problem as it applied to drug control laws, the pharmaceutical section of one Southeast Asian Ministry of Health negotiated with the police department to obtain the authority for its own personnel to investigate and prosecute violations. With enforcement authority vested within the government agency responsible for distribution, greater coordination was possible. However, such a solution would not work if theft were coordinated or condoned at the upper levels of the supply agency.

When stolen drugs are sold through a multitude of street vendors, closing the outlets may not be feasible -- it is too hard to identify them. In these instances, control can be exerted more effectively at the sources of theft, rather than at the outlets.

Figure VI.C.3.

Sampling of Techniques for Theft Control

AT THE PORT

Containerization -- if port is equipped to handle it, reduces both major and petty theft.

Rapid Port Clearance -- inadequate and inefficient port-clearing procedures of some public drug programs result in long delays in the port, providing extended exposure to theft in ports with weak security. Increased efficiency in port clearing reduces theft.

AT THE MEDICAL STORES (central, regional, hospital)

Limited Access -- access to medical stores is limited to the pharmacist, store manager, and store employees. Hospital pharmacies are not accessible evenings, weekends or other times when the pharmacist or dispenser is not present. Limited quantities of extra supplies for emergency room and ward use are entrusted to medical officers or nurses during hours when the pharmacy is closed. Distribution of these supplies must be accounted for.

Secure Locks and Doorways -- essential to good security. Country Study VI.C.2. describes procedures for key control.

Unannounced Searches -- of medical stores and hospital personnel. In some countries the pharmacist or medical director personally supervises periodic, unannounced searches.

Annual Independent Stock-Take -- staff from the central pharmaceutical supply office visit all major medical stores to perform either a complete or a sampling stock-take and verification of receipt and issue records.

DURING TRANSPORT

Document Verification -- receiving clerk held responsible for checking receipts against packing slip. Separate invoice is sent by mail from issuing store and receiving form is verified against this invoice. Document verification uncovers complete disappearance of shipments as well as partial losses in transit.

Packing Seals -- tape, wax seals, wire seals, etc. used to close cardboard boxes or other transport containers do not prevent theft, but make tampering obvious.

Strong Boxes -- when large shipments are made to small numbers of facilities, portable strong boxes or built-in compartments with padlocks are used. One key remains at the issuing store and the other at the receiving store.

IN HOSPITALS

Drug Accounting -- by ward staff and out-patient staff to provide a record of all drugs received and all drugs dispensed. Recording of individual drug orders sometimes restricted to selected drugs (as described in Country Study VI.C.3.).

Issue-Consumption Verification -- for dangerous and controlled drugs, a consumption report indicating the time, date, patient, patient's number, dose, and remaining stock levels must be submitted to the pharmacist with each requisition for additional stocks of these drugs.

Presentation of Prescriptions for Ward Issue -- for selected, expensive, or frequently abused drugs, the hospital pharmacy requires a copy of the signed prescription to be filed with the pharmacy before drugs are issued to the ward.

Rotating Stock Containers -- wards are issued a limited number of labeled containers for each drug which they stock. When ward staff reports to the pharmacy to replenish their stock, these containers must be presented and drugs are issued into containers. The containers allocated for each drug should represent a stock sufficient for several days. Frequent replenishment of stock is cause for suspicion.

Locked Transport Boxes -- drugs are issued by the pharmacy into a wooden or metal box with a padlock. Each ward has its own wooden or metal padlocked box for drugs. The pharmacist has a key for each ward's box and the head nurse on each ward has the second key for that ward's box.

Up-Grading Transport Staff -- several countries have noted improved hospital security as the transport staff has changed from laborers to nursing students, dispensers, or nurses. When the pharmacy establishes a twice or thrice weekly issuing schedule for wards, it becomes more feasible for nursing staff to allocate time to collect drugs from the pharmacy.

Up-Grading Pharmacy Staff -- gradual replacement of untrained laborers with trained pharmacists and dispensers has been credited with decreasing theft in some countries. A combination of more careful screening of individuals, professional socialization, and higher pay appear to explain this observation.

IN OUT-PATIENT DEPARTMENTS AND HEALTH CENTERS

Maximum Dispensing Quantities -- prevent patients from altering prescriptions to obtain large amounts of drugs and prevent collaborating physicians from writing excessively large prescriptions.

Selective Recording of Individual Prescriptions -- is required to increase dispenser accountability for selected "attractive" drugs. Part of drug accounting system similar to that used for inpatients.

Dispensing by Physicians and Auxiliaries -- where the health center aides responsible for dispensing medicines are found to be pilfering certain attractive items, the physician and medical auxiliaries take the responsibility for personally dispensing these selected drugs to patients in their examining rooms.

b. Bribery

Illegal payments from suppliers to purchasing officials can occur at any level where purchasing is done. There are three decisions which the supplier may hope to influence with his bribe: (1) the choice of drugs to be bought, (2) determination of the purchase quantities, and (3) selection of the supplier for each drug. A determined supplier can influence the decision in nearly any system; nevertheless, the establishment of separate mechanisms for making each of these three decisions and the implementation of certain controls on each decision can make the process of influencing decisions much more difficult and more costly.

Influencing the choice of drugs -- Drug selection was discussed earlier (Section II.A.), where it was noted that the participation of a broad spectrum of respected physicians, pharmacists, and public officials often lends credibility to drug selection, while at the same time improving the appropriateness of the selection. Another advantage of using a broadly representative group of professionals, rather than one or two individuals, is that it lends greater visibility to the selection process: it is more difficult for a supplier to induce the purchase of an unnecessary drug or to inappropriately limit the choice to a particular brand name.

Where limited budgets exist for the purchase of drugs at the local level, joint assignment of purchase approval responsibility to the pharmacist and the medical director, combined with the requirement that reasons for outside purchases be documented, may reduce the opportunity for illegal payments to effect a purchase.

Influencing the purchase quantities -- When inventory control is poorly implemented, ordering is usually done on the basis of the best guesses of the purchasing officers. Without consumption data to compare and contrast with these guesses, order quantities which are inflated by bribe-seeking purchasing officers are not easily detected. In contrast, when effective inventory control and forecasting are operating and/or when a systematic method of estimation is used to determine order quantities, it becomes much more difficult for the supplier to influence order quantities.

Figure VI.C.3.

Sampling of Techniques for Theft Control

AT THE PORT

Containerization -- if port is equipped to handle it, reduces both major and petty theft.

Rapid Port Clearance -- inadequate and inefficient port-clearing procedures of some public drug programs result in long delays in the port, providing extended exposure to theft in ports with weak security. Increased efficiency in port clearing reduces theft.

AT THE MEDICAL STORES (central, regional, hospital)

Limited Access -- access to medical stores is limited to the pharmacist, store manager, and store employees. Hospital pharmacies are not accessible evenings, weekends or other times when the pharmacist or dispenser is not present. Limited quantities of extra supplies for emergency room and ward use are entrusted to medical officers or nurses during hours when the pharmacy is closed. Distribution of these supplies must be accounted for.

Secure Locks and Doorways -- essential to good security. Country Study VI.C.2. describes procedures for key control.

Unannounced Searches -- of medical stores and hospital personnel. In some countries the pharmacist or medical director personally supervises periodic, unannounced searches.

Annual Independent Stock-Take -- staff from the central pharmaceutical supply office visit all major medical stores to perform either a complete or a sampling stock-take and verification of receipt and issue records.

DURING TRANSPORT

Document Verification -- receiving clerk held responsible for checking receipts against packing slip. Separate invoice is sent by mail from issuing store and receiving form is verified against this invoice. Document verification uncovers complete disappearance of shipments as well as partial losses in transit.

Packing Seals -- tape, wax seals, wire seals, etc. used to close cardboard boxes or other transport containers do not prevent theft, but make tampering obvious.

Strong Boxes -- when large shipments are made to small numbers of facilities, portable strong boxes or built-in compartments with padlocks are used. One key remains at the issuing store and the other at the receiving store.

IN HOSPITALS

Drug Accounting -- by ward staff and out-patient staff to provide a record of all drugs received and all drugs dispensed. Recording of individual drug orders sometimes restricted to selected drugs (as described in Country Study VI.C.3.).

Issue-Consumption Verification -- for dangerous and controlled drugs, a consumption report indicating the time, date, patient, patient's number, dose, and remaining stock levels must be submitted to the pharmacist with each requisition for additional stocks of these drugs.

Presentation of Prescriptions for Ward Issue -- for selected, expensive, or frequently abused drugs, the hospital pharmacy requires a copy of the signed prescription to be filed with the pharmacy before drugs are issued to the ward.

Rotating Stock Containers -- wards are issued a limited number of labeled containers for each drug which they stock. When ward staff reports to the pharmacy to replenish their stock, these containers must be presented and drugs are issued into containers. The containers allocated for each drug should represent a stock sufficient for several days. Frequent replenishment of stock is cause for suspicion.

Locked Transport Boxes -- drugs are issued by the pharmacy into a wooden or metal box with a padlock. Each ward has its own wooden or metal padlocked box for drugs. The pharmacist has a key for each ward's box and the head nurse on each ward has the second key for that ward's box.

Up-Grading Transport Staff -- several countries have noted improved hospital security as the transport staff has changed from laborers to nursing students, dispensers, or nurses. When the pharmacy establishes a twice or thrice weekly issuing schedule for wards, it becomes more feasible for nursing staff to allocate time to collect drugs from the pharmacy.

Up-Grading Pharmacy Staff -- gradual replacement of untrained laborers with trained pharmacists and dispensers has been credited with decreasing theft in some countries. A combination of more careful screening of individuals, professional socialization, and higher pay appear to explain this observation.

IN OUT-PATIENT DEPARTMENTS AND HEALTH CENTERS

Maximum Dispensing Quantities -- prevent patients from altering prescriptions to obtain large amounts of drugs and prevent collaborating physicians from writing excessively large prescriptions.

Selective Recording of Individual Prescriptions -- is required to increase dispenser accountability for selected "attractive" drugs. Part of drug accounting system similar to that used for inpatients.

Dispensing by Physicians and Auxiliaries -- where the health center aides responsible for dispensing medicines are found to be pilfering certain attractive items, the physician and medical auxiliaries take the responsibility for personally dispensing these selected drugs to patients in their examining rooms.

b. Bribery

Illegal payments from suppliers to purchasing officials can occur at any level where purchasing is done. There are three decisions which the supplier may hope to influence with his bribe: (1) the choice of drugs to be bought, (2) determination of the purchase quantities, and (3) selection of the supplier for each drug. A determined supplier can influence the decision in nearly any system; nevertheless, the establishment of separate mechanisms for making each of these three decisions and the implementation of certain controls on each decision can make the process of influencing decisions much more difficult and more costly.

Influencing the choice of drugs -- Drug selection was discussed earlier (Section II.A.), where it was noted that the participation of a broad spectrum of respected physicians, pharmacists, and public officials often lends credibility to drug selection, while at the same time improving the appropriateness of the selection. Another advantage of using a broadly representative group of professionals, rather than one or two individuals, is that it lends greater visibility to the selection process: it is more difficult for a supplier to induce the purchase of an unnecessary drug or to inappropriately limit the choice to a particular brand name.

Where limited budgets exist for the purchase of drugs at the local level, joint assignment of purchase approval responsibility to the pharmacist and the medical director, combined with the requirement that reasons for outside purchases be documented, may reduce the opportunity for illegal payments to effect a purchase.

Influencing the purchase quantities -- When inventory control is poorly implemented, ordering is usually done on the basis of the best guesses of the purchasing officers. Without consumption data to compare and contrast with these guesses, order quantities which are inflated by bribe-seeking purchasing officers are not easily detected. In contrast, when effective inventory control and forecasting are operating and/or when a systematic method of estimation is used to determine order quantities, it becomes much more difficult for the supplier to influence order quantities.

Country Study VI.C.2.

Security System of the Central Warehouse in Afghanistan

In order to minimize theft and damage of property due to carelessness, the following procedures are suggested for use at the New Warehouse:

1. Every compartment can be locked up. Each section will be the responsibility of one storekeeper or professional trustee.

2. The key to every compartment will normally remain in a locked cabinet in the office of the head storekeeper. The head storekeeper is responsible for seeing that all keys are returned to the cabinet at the end of the working day. He then locks the cabinet and turns the key over to the Warehouse Manager or Deputy Manager. Leaving the compound without returning the key is grounds for dismissal. He must return it to the Head Storekeeper or the Manager or Deputy Manager if the Head Storekeeper is absent. Each storekeeper must name another member of the staff, or the Manager or Deputy as an alternate in the event that his storeroom must be opened in his absence.

3. The only spare keys to the key cabinet and Manager's Office will be in care of the Administration Department.

4. The Storekeepers and the professional trustee(s) will be held accountable for missing or damaged property. Complete and spot inventories will be taken periodically of every storeroom. It therefore will be in the storekeeper's interest to verify the initial quantities entered on the Stock Ledger Cards, and to carefully control and double check exact quantities of all materials entering and leaving his storeroom.

5. The Manager or Deputy will instruct various clerks to randomly take inventories of certain items and will compare the amounts to the most recent balance listed on the Stock Ledger Card. The storekeeper or trustee is not allowed to be in the storeroom at that time, but may return along with the Manager or Deputy if there is a discrepancy.

6. In the event of a discrepancy, either too many or too few of an item counted on the shelf, the Manager or Deputy or the Controller will follow this procedure:

   a. The Manager or Deputy will find all Issue Tickets and Receiving Reports listed on the Stock Ledger Card, and check all the entries and the arithmetic on the cards.

   b. If this does not uncover the error, he will locate all Warehouse Requisitions from which the Issue Tickets had been prepared and check these to see the actual amount which had been issued.

   c. If the storekeeper or trustee cannot adequately explain the discrepancy, the Manager of the Warehouse should recommend that a full investigation be made by the Ministry.

7. The storekeeper or trustee is also responsible for the general condition of his storeroom, so that materials are kept in a safe, clean and orderly manner.

8. The Head Storekeeper must make regular inspections of all storerooms to make sure they are being kept in order and that materials are being properly stored to avoid danger and damage. He may order the storekeeper to make any needed changes and can recommend dismissal if the storekeeper does not perform his job properly.

9. All personnel and vehicles leaving the Warehouse compound will be subject to search by the guard or gatekeeper. This applies to all Warehouse personnel. If any vehicle or person enters the compound with an article of value, he must either show it to the guard, leave it in the guardhouse, or get a note from the guard, in order to be allowed to leave with it.

   Any object taken from the warehouse must either be accounted for by a signed issue ticket, a release note from the Manager or Deputy Manager, or have been checked by the guard upon entry. The Manager or Deputy shall be summoned immediately upon discovery of an unauthorized object leaving the warehouse.

Source: Excerpts from The Management Team, Ministry of Health: New Central Warehouse System and Regulations Concerning Receiving, Issuing, and Return of Goods.
Boston: Management Sciences for Health, 1975.

Country Study VI.C.3.

Drug Accounting in Sri Lanka

Government health facilities have modified a detailed drug accounting system from British colonial times to help economize on drug use.

1. Drug Accounting

At each step where drugs are transferred from one level to the next (e.g., divisional stores to institution storeroom), a ledger is kept and complete entries are made for each transaction, including date, to/from whom, and amount issued/received. At the point of dispensing (either to outpatients or on the wards), dispensing records are kept in one of two ways, depending on the type of drug:

a. Accountable Drugs, which include (1) antibiotics, (2) drugs costing more than U.S.$0.003 per unit and/or (3) controlled substances (narcotics, etc.), must be accounted for individually. A serial record including the patients's health service number, type of drug, number of units dispensed, and date, is kept in a log book. Total amounts recorded in the prescription log must be balanced daily or weekly with stock records.

b. Bulk Drugs, which consist of all those items not in group a., are charged out to the dispenser, floor nurse, or doctor in bulk, usually in units equivalent to container size (e.g., 1000 tablets of ASA in a tin are recorded as 1 bulk item). Recording of individual drug issues is unnecessary for these items.

2. Auditing

Drug distribution and dispensing records are generally audited by the Ministry of Health Internal Audit once a year at major institutions. Receipts and issues are checked at all levels, including at the window of the dispensary.

3. Test-checks

Periodically, test-checks are conducted by the medical officer in charge, someone delegated by him, or, at larger institutions, the chief of nursing. Without warning the checker compares the book balance and physical stock for about ten items. The form is prepared in triplicate, with one copy to the medical officer, one to the division's Superintendent of Health Services and one to the Ministry's Internal Audit.

Ward test-checks should be done about every two weeks and outpatient dispensary checks once a month.

Influencing supplier selection -- The selection of the supplier for each item to be purchased is the last decision which potential suppliers may attempt to influence. As with the selection of drugs, the selection of suppliers appears to be improved when made by carefully chosen tender boards. Furthermore, the requirement that selection based on factors other than price be fully explained will discourage inappropriate choices.

c. Fraud

Fraud on the part of manufacturers and importers who dilute liquid preparations, omit expensive active ingredients, or short-pack their shipments should generally be uncovered by proper quality assurance practices and thorough receipt-checks by the receiving clerk at the medical stores or pharmacy.

Stock clerks should be held accountable for the complete and accurate preparation of receiving reports. The accuracy of these reports should be periodically checked by supervisory personnel.

Inadequate funding for warehouse staff and inadequate staff training and supervision are often responsible for poor performance of receipt-checking activities. Any savings in salaries and training costs can be lost several times over if, as a result of these savings, supplier fraud escapes detection by warehouse staff.

When Performance Guarantees or Retention Money is involved (Section III.B.), the supplier can be more readily held accountable for both intentional errors (i.e., fraud) as well as unintentional errors in formulation or packing. Precise specification of product requirements and rigid enforcement of these contract requirements are important parts of the procurement process.

3. THE COST OF SECURITY

Many methods for preventing breaches in security serve a dual purpose in that they are necessary activities in effective drug purchase and distribution; they do not represent security expenses *per se*. Examples of these activities are establishment of a drug selection committee, quality assurance, inventory control and forecasting, and receipt-checking.

On the other hand, some security functions are quite costly. Imprinting of containers, embossing of tablets and capsules, hiring of special security staff, purchasing of padlocks, construction of secure warehouses and storerooms, training of stock clerks, and individual recording of all drug issues can be expensive. These expenses must be weighted against the potential savings from reduced theft, bribery, and fraud. All of these breaches in security can have substantial medical as well as financial costs.

Bribery can be particularly costly to a drug program in financial terms. Not only does the program pay the supplier higher prices for drugs, to cover the cost of the bribe, but it also pays for large quantities of unneeded drugs. Fraud, on the other hand, may have serious and even life-threatening medical consequences if the supplier has chosen to use smaller amounts of the active ingredients. *Theft* raises drug program costs by increasing the volume of drugs that are purchased and also has medical costs resulting from shortages and the improper use of drugs, (e.g., increased bacterial resistance resulting from frequent short-term use of antibiotics).

Comparing the monetary cost of breaches in security to the cost of security measures is particularly impressive when it is understood that over-purchasing is paid for in many countries by limited foreign exchange allocations, while expenditures for security occur mostly within the country.

When weighted against the losses resulting from theft, illegal payments, and fraud, the cost of adequate security measures may be found to be well justified.

SUMMARY

Security breaches include theft, bribery and fraud.

Security breaches can have a substantial -- sometimes overwhelming -- economic and health impact.

A comprehensive security system includes:

(1) Analysis of the sources of security breaches
(2) Determination of methods to improve security
(3) Implementing security measures after consideration of cost/savings tradeoffs.

Security breaches can be found through:

(1) Informal investigation
(2) Independent stock-takes
(3) Consumption comparisons
(4) Survey of drug outlets.

Theft prevention requires:

(1) Unique identifiers for all government drug supplies
(2) Attacking the sources of government theft
(3) Closing the outlets for stolen drugs.

Controlling bribery requires institution of mechanisms to prevent supplier influence on:

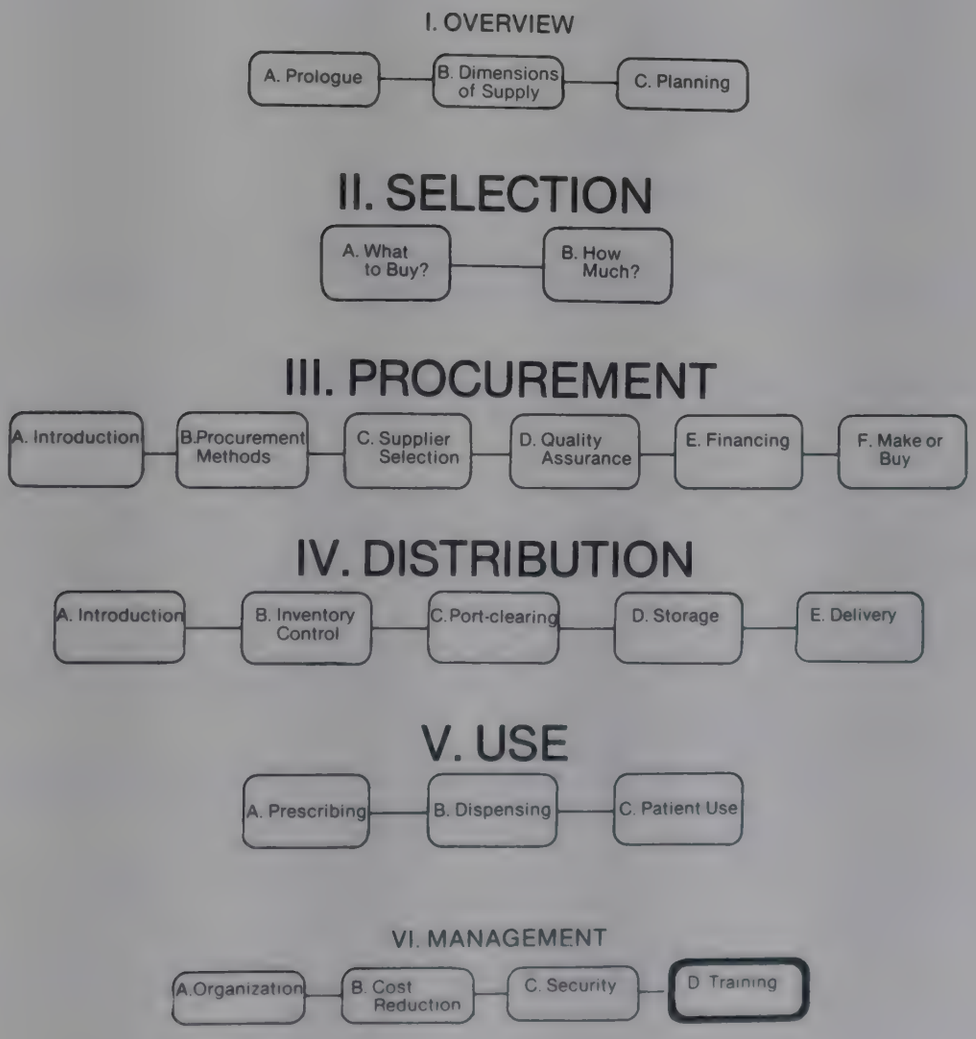
(1) Choice of drugs
(2) Determination of purchase quantities
(3) Supplier selection.

Control of fraud requires close attention to quality assurance procedures and routine stock-control procedures.

Security measures may be costly, but when the true cost of security breaches is considered, adequate security is generally less costly.

Chapter VI.D.

Designing Training Programs to Improve Pharmaceutical Logistics



	Page
1. WHY TRAIN?	531
2. GENERAL PRINCIPLES	532
3. PROGRAM CHARACTERISTICS	534
a. Long-Term Training	534
b. Short-Term Training	534
c. Observation Trips	537
d. Conferences and Seminars	537
e. In-Country Counterpart Training	539
4. OBTAINING ASSISTANCE FOR THE DESIGN AND IMPLEMENTATION OF TRAINING PROGRAMS	539
5. DEVELOPING TRAINING PLANS	539
SUMMARY	542
REFERENCES	543
APPENDICES	
VI.D.1. Training Objectives for Three Levels of Personnel	544
VI.D.2. Sources of Assistance for Training Programs to Improve Pharmaceutical Logistics	547

Designing Training Programs to Improve Pharmaceutical Logistics

Training is defined broadly as any activity that transfers knowledge and skills to developing country public health personnel to improve the functioning of the supply system. The training can be formal or non-formal; academic or observational; in public agencies or private institutions. Training is a dynamic process, not static. Although initial training will be necessary to improve performance, continuing education and support of graduates is required to maintain skills. This must be included in initial training plans.

Assessment Guide VI.D. is a guide to help determine the needs for training of personnel within the drug supply system. It also raises issues of what kinds of training programs are needed, where training is available, and how appropriate programs can be developed.

Before discussing training programs in detail, it will be helpful to review the purposes of training programs for pharmaceutical logistics personnel.

1. WHY TRAIN?

The training of public sector personnel in pharmaceutical logistics will have four major objectives:

(1) To increase their knowledge about the special needs of pharmaceutical logistics.

(2) To change their attitudes about the importance of logistics and each individual activity to the overall impact of public health programs, thus improving the environment for change.

(3) To improve skills in the specific tasks that need to be completed for efficient functioning of the logistics system.

(4) To improve job behavior, so that people function better at their assigned activities.

The training needs to be directed at three levels of personnel:

- policy-makers, who are responsible for creating the environment needed for improved logistics performance;
- mid-level managers, who are responsible for supervising the various activities required in the logistics process; and
- line personnel, who are responsible for implementing the specific changes that will be required.

ASSESSMENT GUIDE VI.D.
Assessing Training Requirements

- Have the personnel in key posts had any specific training for the tasks they perform?
- What are the major deficiencies of the logistics system in the country? Which of these problem areas could be addressed through better-trained personnel (rather than through better facilities or equipment)?
- What are the major target groups for training? What is the background (education, experience) of the proposed participants?
- What training programs exist that will meet the deficiencies noted and are appropriate to the background of the participants? What resources exist for funding and providing technical assistance for the development of new programs?
- Does the agency (ministry, program) environment facilitate changes? What post-training support will be needed by participants? What is the best training plan that will meet all the needs within the limits of the resources identified above?

Specific objectives for each level of personnel are outlined in Appendix VI.D.1. It is important to stress that training alone will not result in significantly improved logistics performance unless it is linked with changes in policy, organizational structure, procedures, and resource allocations discussed in previous sections.

Country Study VI.D.1. gives an example of integrating training into overall program changes in one pharmaceutical supply system.

2. GENERAL PRINCIPLES

The training strategies that are developed must be appropriate to the educational level of personnel, relevant to the resources available in the country, and feasible in terms of the amount of time and travel involved. Government officials may be placed in positions of responsibility for which they have little formal education, and training programs must reflect this fact. Programs must also consider resources available: an official in inventory control who uses a simple card system should be trained in the operation of that system rather than a computerized system. Training programs must be feasible, and recognize that governments may lack sufficient organizational depth to allow a senior official to take an extended training leave, regardless of potential long-term benefits. For some of the most critical

Country Study VI.D.1.

Implementing Change in a Pharmaceutical Supply System

Country Study III.E.5. describes the Montero Project's initial attempt to establish a drug sales program. As a result of the program's failure, the Project made special effort to rebuild its entire supply and also make a fresh start in drug sales. Working with an outside consultant, the Project staff began with a formal analysis of the system as it had previously functioned. This analysis produced a list of deficiencies to be corrected, but it also concluded that some of the basic policies and organizational features of the system should be retained. In particular, emphasis on community organization was continued and the Basic Health Unit remained the focal point of distribution.

The Implementation Team -- The responsibility for developing a complete system design was delegated to an implementation team composed of two staff members and the consultant. Paying special attention to the deficiencies identified in the analysis, the team began with fundamental management issues such as establishing delivery intervals, stock requirements, and inventory control mechanisms. Procedures and forms were then developed for performing all supply-related tasks. The team also specified policies and procedures for the drug sales program, focusing upon community participation, financial accountability, and price setting. Finally, the specific responsibilities of both Project staff members and health workers were defined. At each level of the system, all decisions, procedures, and paperwork were assigned to a responsible person.

Preparation of an Operations Manual -- The tangible result of the planning effort was the production of an operations manual. (The role of this type of document in implementation efforts is frequently misunderstood; sometimes producing a manual is actually equated with implementation.) In Montero, its primary value was as a guide for identifying, prioritizing, and scheduling the activities necessary for implementation. Among these were setting up an improved supply information system, organizing the newly built warehouse, procuring drugs, setting up a prepackaging operation, training personnel, and restocking Basic Health Units.

Emphasis on Training -- The implementation team assigned highest priority to training. At the Project's central level there was little need for formal training programs, but close supervision of all activities by nurse auxiliaries and other experienced staff was necessary. The critical training effort was with the training in managing their stock or in filling out the forms that go along with requisitioning and dispensing drugs. The health promoters received their supplies from their supervising auxiliary at the health post. It appeared that this had occurred haphazardly; the new design organized this activity so that all promoters came to the health post on the same day and worked team style with the auxiliary to systematically fill each requisition.

A Seminar for Health Workers -- The implementation team also shared concerns over health workers' perception of the objectives of the sales program, its potential for bringing low cost, effective drugs to rural communities, and the health workers' own role in promoting the safe use of these drugs. With the goal of preparing the auxiliaries and health promoters to manage their stock efficiently and to forward requisitions and money from sales promptly, the implementation team organized a three-day seminar that focused strictly on supply-related problems. This also provided an opportunity to test forms and receive suggestions for simplifying them.

The seminar, attended by approximately fifty health workers, covered the following subjects: instruction on filling out forms, followed by supervised practice sessions in which hypothetical problems were posed and worked out; the concept of prepackaged courses of treatment, stock handling, and shelf arrangement; and the new routine for supplying health promoters. Demonstration shelves were set up with supplies neatly arranged in the order they appeared on requisitions. Members of different Basic Health Units role-played the resupply routines. In addition, health workers were given checklists of the supply-related activities for which they were responsible. The activities were briefly stated and ordered in the sequence in which they should occur. The activity that provoked the liveliest exchange was small group discussion of the role of the drug sales program and the role of health workers in promoting sales. The health workers made it clear that persuading people to buy drugs was not an easy matter. Price was repeatedly mentioned as the major problem. The discussions provided some useful insights into the motivation and morale of both auxiliaries and health promoters.

Results -- The seminar appeared to produce positive results: 4 out of 6 of the first round of requisitions were properly filled out, and another was close to correct. Supervisory follow-up was provided as quickly as possible to auxiliaries who were having trouble with their requisitions. When the Project began to deliver fresh stock for the redesigned program, an implementation team member accompanied by one of the project's regular supervisors participated in each delivery. Working with the health post auxiliary, the two helped to arrange shelves, to see that all files were set up, and to make sure all stock was properly stored. Follow-up visits to inspect storage conditions and files were encouraging: 5 out of 6 health posts were in good order.

positions, it may not be possible for officials to be absent for more than one week, if at all.

Thus, proposed training programs must be considered in light of the special circumstances of a particular country which determine the appropriateness, relevance, and feasibility of any training effort. The training needs should be determined by a frank assessment of the pharmaceutical supply system in that country.

Figure VI.D.1. lists the subject areas, topics, and relevant target groups that should be considered. Some of these areas may already be strong points of the system and may not need additional consideration. Other areas may be identified as major weaknesses, and that is where the training should be focused, both in terms of the course content and the participants.

3. PROGRAM CHARACTERISTICS

The development of a training program to meet specific needs takes into consideration several factors, each offering multiple options, which are presented in Figure VI.D.2.

Considering all these factors, in practice, several major options for training emerge:

a. Long-term training in overseas institutions, in academic or non-academic settings, will be most useful in highly technical areas, such as research and development of new drugs, quality assurance, local production, or improved manufacturing practices. The use of fellowships is most appropriate here for M.D.s, pharmacists, industrial engineers, or other highly technical professionals

This approach is limited by various factors. At present, there are not enough long-term training programs sufficiently developed to meet the training needs. Long-term training requires political stability in the trainee's home country; in some countries, a person may be absent 1-2 years for advanced training only to find he/she does not have a position available upon return due to political changes. In addition, long-term training removes valuable human resources from a public health system that probably has a scarcity of good people. Finally, people who receive advanced training and/or degrees often find the conditions under which they previously worked to be unacceptable upon return, and they often leave for more lucrative positions outside the public sector or in other countries. Replacement costs for retraining new personnel can be quite high.

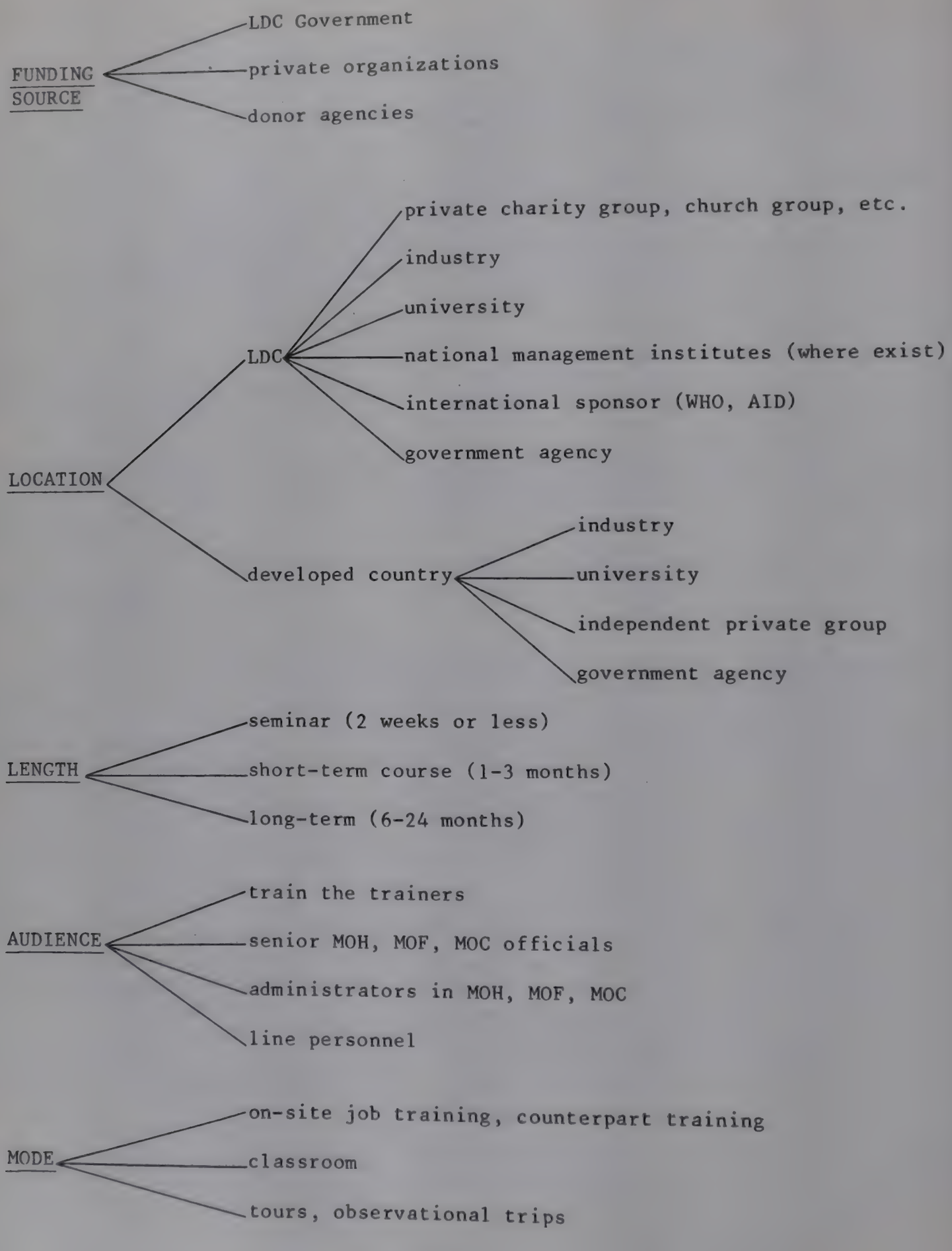
b. Short-term training of one to three months may be arranged in academic or non-academic settings in the same country or in overseas institutions. For short-term training to work effectively, the trainee often needs to be separated from everyday work responsibilities. This can occur in a separate area of the trainee's own country or can be arranged in another country.

Subject Areas, Training Needs, and Target Groups

SUBJECT AREA	TOPICS	TARGET GROUPS
SELECTION	Public Formulary Sources of Information Safety/Efficacy Cost Comparisons Levels-of-Use	Policy and decision makers in: MOH MOF Other involved Ministries Service Providers: Doctors Nurses Auxiliary Personnel Pharmacists/Dispensers
PROCUREMENT	Procurement Cycle Forecasting Purchasing Methods Scheduling Purchases Terms of Payment Selecting Suppliers Payment Mechanisms Organizing Procurement Services Quality Assurance Make or Buy Decisions	Division of Planning, MOH Division of Finance, MOH Division of Administration or Purchasing, MOH Ministry of Finance Central Procurement Service (if exists) Central Laboratories, MOH Food and Drug Administration (if exists) Senior MOH/MOF officials for policy decisions (e.g., Make or Buy)
DISTRIBUTION	Logistics Cycle Information System Port Clearing Warehousing Operations Packaging/Repackaging Transportation Security	Division of Planning, MOH Division of Administration, MOH Operations Personnel in: Port Warehouses (Central and Regional) Transportation
USE	Promotion of Appropriate Therapy Training of Health Workers Dispensing Practices Patient Education Information System Patient Compliance	Program Directors Program Supervisors Doctors Nurses Pharmacists Dispensers Auxiliary & Community Health Workers

Figure VI.D.2.

Issues to Consider in Designing Logistics Training Program



This approach is appropriate for all the training needs in pharmaceutical logistics, especially for top and middle level personnel. Several prerequisites exist for short-term training to be effective, including:

- a sufficient supply of people with initial background training;
- courses available in the language of the participants;
- course design using training modules to allow for flexible curricula to meet the individual needs of different target groups;
- intensive, practical training so that a good deal of information and skills are gained in a short period of time; and
- adequate follow-up of graduates to ensure continued functioning in the field, including continuing education programs.

In addition to training the target groups outlined in Figure VI.D.1, this type of program is good for the training of trainers, i.e., people who will return to their own country and train others in the techniques and skills they have learned. Thus, short-term training should also include pedagogical and leadership skills, and provide some institution-building capacities.

The major limitation of this approach is that there are as yet no institutions or training materials fully developed to provide the broad range of courses needed, either on a regional or international scale. Some private non-governmental institutions in the U.S. and Europe have done some of this training on a limited scale in individual countries. In addition, some institutions are beginning to take steps toward development of regional training centers in management, but these are not necessarily oriented to public health programs. Additional resources will be needed by either of these types of institutions to further develop their programs.

c. Observation trips to functioning programs in overseas locations are a third alternative. Some countries have successfully implemented parts of a pharmaceutical logistics system, but have no formal training program. They can serve as useful and practical examples for personnel from other countries. In addition, some of the multinational pharmaceutical manufacturers have regional warehouses, manufacturing plants, laboratories, etc., that could make good sites for visits. Observation trips work best when combined with short-term training. When visits occur after training, and trainees are accompanied by their trainer, they can serve to reinforce in a practical way the skills learned.

d. Conferences and seminars can be presented on a regional basis to public health personnel using standardized curricula prepared and presented by an international institution. This approach works well for focusing individual attention on particular components, such as distribution or use. It is also very effective in promotion of lengthier training programs, information-sharing among developing countries, and general sensitization of policy makers to the importance of the logistics process along with motivating desire for improvement.

Figure VI.D.3.

Glossary of Training Terminology

A sound training plan is based on concepts that use terms whose context may be different from normal usage. These are clarified below:

Training Program -- A planned series of activities designed to help participants develop knowledge and skills they need for effective performance of their jobs.

Post-training Support -- Provision of assistance to training program graduates in the utilization of new skills. Although training can contribute to improved job performance, a training program alone can rarely accomplish major changes; the program should be supplemented by post-training support. Forms of assistance may include on-site consultation, continuous contact and development of networks among graduates, and periodic refresher training.

Target Groups -- Those people whose improved knowledge and skills can affect the implementation of changes in pharmaceutical logistics systems in developing countries.

a. Policy-makers: Those at the top of the organization whose approval is important for agency-wide changes to occur (e.g. Ministers, Vice-ministers, Director-Generals, and Secretaries).

b. Top Managers: Those responsible for the smooth functioning of major divisions; overall operations of the health programs and delivery of services; development of policies and decisions which affect their programs and divisions; and on-going supervision of operations personnel.

c. Operations Personnel: Those staff responsible for the hands-on, day-to-day tasks of the pharmaceutical logistics system.

Institution-building -- The process by which an organization or division of the Ministry is developed so that it has the capability to conduct training programs and serve as a resource on pharmaceutical supply systems management. This may include training of staff, technical assistance to the institution, provision of the equipment and supplies needed for conducting the training, and on-going guidance.

Training Modules -- A training module is a package of training information that includes the following components:

- A carefully planned curriculum based on job analysis and training by objectives so that, for common skills, workers of the same level receive the same knowledge, attitudes, and skills in each program or country of the region;
- A curriculum that has a series of sub-modules (or sub-curricula) that are different from the common skills taught to each worker at the same level, so that workers from each program or country can choose special skills that are "tailor-made" for their particular needs;
- A teaching guide for users of the module that informs them on how to use the module to accomplish teaching objectives;
- Training materials necessary to teach.

Evaluation -- The process of gathering information in order to assess the performance (effectiveness) of key aspects of the training programs, such as materials, methodology, trainers, and participants, and to make decisions about the changes needed to increase training effectiveness.

a. External Evaluation: Evaluation conducted by persons who have not had a previous role in the project.

b. Participant Evaluation: Involves the participants in the training process to assess the effectiveness of the program in meeting their needs.

c. Performance Evaluation: Uses both testing and observational techniques to document that students have learned the skills at a level of competence to meet the objectives of the project.

e. In-country counterpart training consists of using outside consultants, whereby an individual with expertise in pharmaceutical logistics (or in one specific component where the need is great) is sent to train counterparts by working on-site for a period of months.

Short-term consultancies work best when focused on a specific activity, e.g., a drug packaging process or the development of an operations manual. Longer periods of time (up to 2-4 years) are required for overall systems renovation. Meaningful improvements in pharmaceutical logistics systems can be made using on-site consultants. The major limitations are:

- Expense -- international agencies characteristically use U.S.$7,000 - $10,000/month to support a consultant in-country.
- Lack of regional effect -- only the individual country benefits, although, conceivably, this country program could train others.
- Lack of appropriate institution-building that allows the host country to successfully continue new innovations after departure of the consultant.

4. OBTAINING ASSISTANCE FOR THE DESIGN AND IMPLEMENTATION OF TRAINING PROGRAMS

A valuable resource for any proposed training program is the practical experience of numerous organizations and institutions in elements of the pharmaceutical supply process. Among these are international organizations, government and non-governmental organizations, universities, developing country institutions, and programs already operating in developing countries.

With few exceptions, these organizations have placed their first priority on service, not training. Training programs have usually been established on an ad hoc basis to fulfill specific current needs, rather than in a systematic and comprehensive way. However, there are notable exceptions where effective training exists in specific areas for a particular level in the supply system or at multiple levels in a vertical disease control program.

Appendix VI.D.2. contains a listing of the organizations that have practical experience in the design and/or implementation of training programs. These organizations can be invaluable resources in the development of many types of training programs.

5. DEVELOPING TRAINING PLANS

The type of training plan developed by any country will depend on several factors:

(1) Assessment of current logistics system(s) and the number and types of deficiencies noted;

Country Study VI.D.2.

Pharmaceutical Logistics Training Strategy

This plan for a Pilot Training Project grew out of a desire to improve the competency of all levels of personnel involved in pharmaceutical supply systems and to correct the deficiencies of past attempts at supply system improvement. In this approach, one region is to be selected, and, within that region, a training institution, which could be developed as a resource for training, post-training support to graduates, and periodic technical assistance in pharmaceutical logistics.

The training programs are to be developed in modules, or discrete curriculum packages, which can be delivered alone or in combination with other modules, as indicated by the needs of the participants. Training is to be provided to key personnel at all levels of public sector organizations: policy-makers, top managers, and operations personnel. Each program will be oriented to the specific needs of the target group and their roles in the pharmaceutical logistics system. The training institution will respond to turnover of staff by offering training programs on a periodic basis and will provide advanced programs for those staff who need to upgrade their skills. Above all, the training will be provided in a setting and culture that is similar to conditions in the home country of the trainees.

1. STRATEGY

The strategy presented here is based on sound training principles that include a needs assesment process to determine the type of programs that will be developed, along with periodic evaluations (both internal and external) to ensure that the training program continues to meet the needs of the participants. The ultimate goal is to have the graduates function within improved pharmaceutical logistics systems with periodic support from the training institution.

The assessment phase will have two components:

- An institutional assessment, whereby training institutions within the selected region are evaluated for their potential development as a Regional Training Center (RTC) in pharmaceutical logistics. One institution will be selected to be the "mother" training center that could eventually provide technical assistance and support to several smaller country institutions or programs.

- A needs assessment, whereby each of the countries within the region will be visited by a team consisting of agency staff, RTC staff, and consultants to assess the state of their public sector pharmaceutical logistics systems. The strengths and weaknesses of each will be assessed, and major needs that are identified will set the priorities for the first year of the program.

The curriculum development phase will follow the needs assessment. Programs will be developed for three categories of public health personnel:

a. Policy-makers: This program will be designed to improve the environment in which logistics improvements must be made. By gaining the support of the top-level decision makers and incorporating their input into subsequent programs, the chance that new skills will be implemented by the other categories of trainees is maximized. This program will provide a general overview of the logistics process and identify critical decision points where policy needs to be made.

b. Top Managers: The policy-level participants will identify the key managers within their programs who will be responsible for planning and supervising logistics improvements. This program will be more detailed and intensive, but is still designed to give an overview of the logistics process, highlighting the critical deficiencies noted during the needs assessment.

c. Operations Personnel: It is at this level where the very detailed training will occur, since these are the people responsible for the daily functioning of the logistics system. Approximately three months of training will be needed to completely train any one individual in all aspects of the logistics process.

Figure A shows a model of this training strategy.

2. CURRICULUM MODULES

The suggested content for each training module and its target audience are presented in Figure B. Although some of the curriculum content may change during the needs assessment phase described above, experience suggests that there are problems which are common to most countries. A preliminary lesson plan is needed for programming and budgeting purposes.

Note that for each target group, three levels of courses are envisioned, for (1) top policy-makers and key decision-makers, (2) top managers who supervise logistics functions, and (3) operations personnel whose full-time job is to perform specific functions in the logistics process.

FIGURE A: Training Strategy

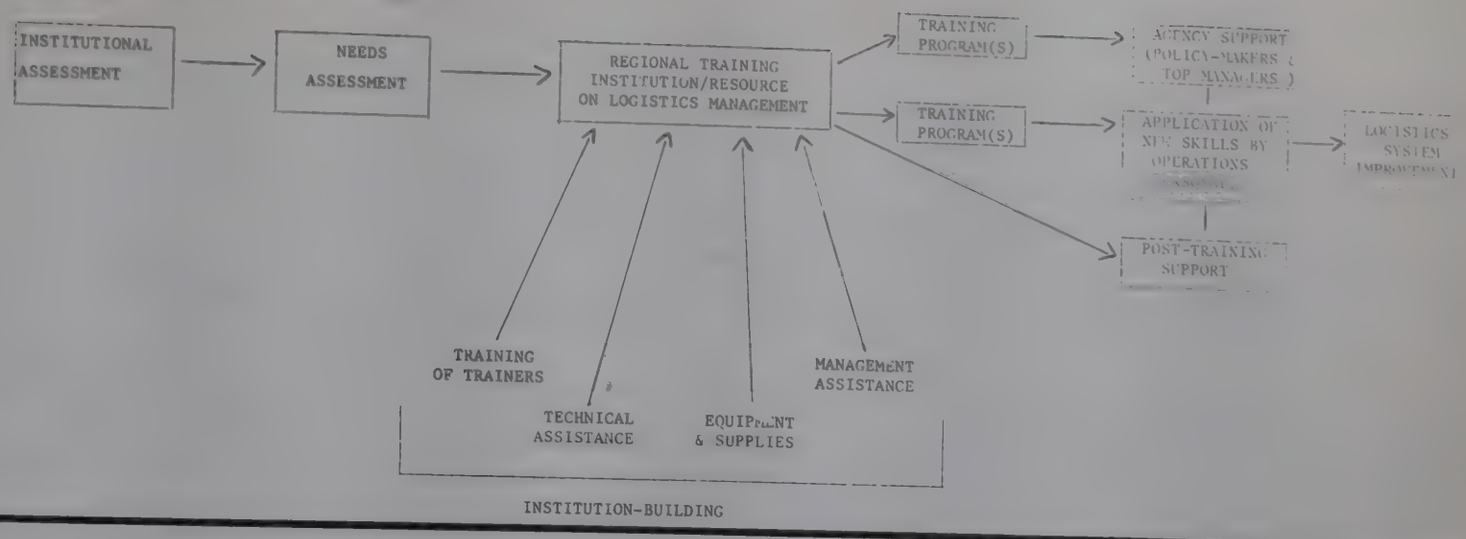


FIGURE B: Suggested Curriculum

SUGGESTED CURRICULUM

SUBJECT AREA	MODULE CONTENT	TARGET GROUP	TIME
PROCUREMENT	Procurement Cycle Purchasing Methods Scheduling Purchases Terms of Payment Selecting Suppliers Payment Mechanisms Organizing Procurement Services	Div. of Planning/MOH Div. of Purchasing/MOH Div. of Finance/MOH Ministry of Finance Central Procurement Service (if present)	Policy: 1 day Managers: 1 week Operations: 1 mo.
	Quality Assurance	Central Laboratories/ MOH	Variable
	Make or Buy Decisions	Minister/Secretary of Health Dir. Gen. Health Dir. Planning Dir. Admin.	Variable
DISTRIBUTION	Logistics Cycle Information Systems Other Aspects Distribution	Planning/MOH Administration/MOH	Policy: 1 day Managers: 1 week
	Information Systems Port Clearing Warehousing Operations Transportation	Operations Personnel in: Port Warehouses Central & Regional Transportation	Operations 1 month
UTILIZATION	Promotion Appropriate Therapy Training of Health Workers Dispensing Practices Patient Education	Program Directors Program Supervisors Doctors Nurses Auxiliary Health Workers Pharmacists Dispensers	Policy: 1 day for all modules Managers: 1 week for all modules Operations: Training=2 wks. Dispensing=2 wks. Patient Education = 1 wk.
SELECTION	Public Formulary Information Sources Safety/Efficacy	Policy & Decision-Makers in: MOH MOF Other involved Ministries	Policy: 1 day Managers: 1 wk. + Technical Assistance Needed for Implementation

TOTAL MODULE TIME:
Policy Level: 4 days (approx. 1 wk.)
Managerial Level: 4 weeks
Operations: 3½ months

The policy level course can be given at one time. The managerial and operations level courses can be given at one time, or they can be divided and given at intervals over several years.

(2) What institutions or agencies exist that can do the training needed to improve these deficiencies (see Appendix VI.D.1.);

(3) What sources of support exist for funding or technical assistance;

(4) The types of people selected for training and their prior preparation (education, experience);

(5) The agency environment in which they work, e.g., what support exists for implementing improvements after completion of training.

Each country or public program needs to assess its own logistics system and develop an individualized plan for training, as there is no single strategy that will be appropriate for every situation. The glossary of training terms in Figure VI.D.3. presents concepts that should be considered in planning. Country Study VI.D.2. offers a sample training strategy; although its aim was a training program for an entire region, the concepts that underlie it are equally appropriate to the individual country setting.

SUMMARY

The training of pharmaceutical logistics personnel has four major objectives:

(1) To increase their knowledge about pharmaceutical logistics;
(2) To change their attitudes about the importance of logistics, and thus improve the environment for change;
(3) To improve skills in specific tasks;
(4) To improve job behavior.

Training must be directed at policy-makers, mid-level managers, and line personnel.

Training strategies should be appropriate to the educational level of personnel, relevant to the resources available, and feasible in terms of the amount of time and travel involved.

Major options for training programs are:

(1) Long-term training -- usually in overseas institutions; most useful in highly technical areas; may mean long-term vacancies in posts.
(2) Short-term training -- in country or overseas; useful for top and middle level personnel and for training of trainers; good training materials lacking.
(3) Observation trips -- to functioning programs in overseas locations; best when combined with short-term training, may reinforce skills learned.
(4) Conferences and seminars -- often on a regional basis; useful for focusing attention on specific topics, for promoting lengthier training programs, for sensitizing policy-makers to the importance of the logistics process.

(5) In-country counterpart training -- using outside consultants; works best when focused on specific activity; limitations include costs, lack of regional effect, and lack of institution-building effect.

Assistance in designing and implementing training programs may be obtained from international organizations, government and non-governmental organizations, universities, developing country institutions, and existing programs.

The type of training developed by a country will depend on:

- the current logistics system and its deficiencies
- the types of training assistance available
- the funding or technical assistance available
- target personnel
- the work environment of target personnel, and its capacity to sustain changes.

Chapter VI.D. REFERENCES

Guilbert, J.J.: Educational Handbook for Health Personnel. Geneva: World Health Organizataon, 1977.

United Nations Development Programme: Directory of Services for Technical Co-operation Among Developing Countries. New York: United Nations, 1978.

UNIDO: Guide to Training Opportunities for Industrial Development. English/French/Spanish. Vienna: United Nations Industrial Development Organization, 1978.

UNIDO: Manual on the Use of Consultants in Developing Countries. Vienna: United Nations Industrial Development Organization, 1972.

Appendix VI.D.1.

Training Objectives for Three Levels of Personnel

CHART 1

Training Objectives
for
Senior Ministry Officials of the
Rank of Director and Above

Knowledge Objectives

- Understand formulation, implementation and evaluation of policy
- Understand environmental analysis, generating, evaluating, and choosing among alternatives
- Understand the process of converting policy into specific tasks and targets for any given organization structure and responsibilities
- Understand the development and use of feedback
- Understand the design and implementation of organization change
- Understand human behavior in organizations

Skill Objectives

- Know how to develop and implement a management control system
- Know how to design and implement a management information and reporting system
- Know how to prepare or evaluate a project proposal, say for giving a motorcycle to each vaccinator/sanitarian
- Know how to prepare and update a manual of instructions for a job or for a specific task at the hospital/basic health center
- Know how to handle the personal and organizational problems associated with change

Attitude Objectives

- Feel that the field personnel should be helped and motivated to achieve organizational objectives
- Feel that the policy makers would improve performance by using analytical data and experience
- Feel that they play a crucial backstage role by being in the middle and helping policy makers and action personnel understand each other's problems
- Feel that they need to know first-hand the field problems as well as the dilemmas of the policy makers and use this knowledge to achieve the ends of policy

Job Behavior Objectives

- Obtain complete and accurate data promptly on pre-specified periodic reports. Identify, analyze deviations and suggest corrective action both upwards and downwards.
- Handle at least 80 to 90 percent of the cases of transfers, promotion, property maintenance and logistics requests, through pre-specified rules, procedures and budgets.
- Reduce exceptions to the bare minimum by communicating effectively and gaining acceptance in advance for the policies, procedures and methods. Consistent, equitable and humane enforcement of explicit rules, procedures/exceptions would enhance all round confidence and reduce exceptions.
- Develop the confidence of both the policy makers and the field personnel through his integrity in using his middle position to the ends of public policy.

CHART 2

Training Objectives
for
Doctors and Other Senior Professionals
Holding Responsible Administrative Positions

Knowledge Objectives

- Understand concepts of motivation and leadership
- Understand the processess of human behavior in organizations (McGregor, Lawrence & Lorsch) and organizational climate
- Understand Environmental Analysis, Assessment of Community Needs and Formulation and Implementation of Policy
- Understand the Ministry policies regarding accounting, audit, purchase, personnel and property

Skill Objectives

- Know how to use effectively the administrative and other professional staff within the policies and procedures of the Ministry
- Know the importance of reporting systems for proper policy formulation
- Know how to motivate, evaluate and supervise personnel with different professional backgrounds
- Know some elements of office management, inventory and accounting control

Attitude Objectives

- Feel that he is a leader and manager and can direct, influence and control all the staff towards desired objectives
- Feel that the Ministry officials need to be apprised of field problems and unique aspects of each unit so that proper policies and exception procedures are evolved
- Feel that they are public servants primarily at the service of the poor and the needy
- Feel that they are professionals and dependent on the effective working of other professionals - nursing, pharmacy, sanitarians, etc.

Job Behavior Objectives

- Give effective management direction and effective* time each day to the hospital and basic health centers
- Supervise, direct and control all aspects of the health services including buildings, medical equipment, inventory, quality of service, personnel motivation and morale.

---

*The word effective is used here to differentiate it from actual time spent.

CHART 3

Training Objectives
for
Line Personnel

Knowledge Objectives

- Understand their role as a change agent
- Understand the concept of participative management
- Understand importance of information and reporting systems
- Understand the role of personal motivation in job achievement

Skill Objectives

- Know how to maintain records and register properly
- Know how to communicate with the clients and influence them
- Know how to plan their activities
- Know how to set goals for themselves in terms of quality and quantity of service

Attitude Objectives

- Feel a sense of pride in being a change agent in the society
- Feel responsible for achieving the targets set for themselves
- Feel responsible for the facilities and equipments provided by the Ministry

Job Behavior Objectives

- Maintain clean premises at the health center
- Send timely and accurate reports
- Enlist the active support and cooperation of community leaders
- Function actively to achieve the stated targets

Sources of Assistance for Training Programs to Improve Pharmaceutical Logistics

The following organizations and institutions offer training in selected activities appropriate to the pharmaceutical supply process. This listing is not exhaustive, nor is it an endorsement of individual training programs. For details, these organizations should be contacted directly.

This listing is arranged with international organizations listed first, followed by national and private organizations and institutions listed alphabetically by the country in which they are located.

International Organizations

World Health Organization, Drug Policies and Management, 1211 Geneva 27 Switzerland, CABLE: UNISANTE, GENEVA

Sponsors seminars and technical discussions. Its Action Programme on Essential Drugs aims to (1) strengthen national capabilities of developing countries in the selection, procurement, distribution, and use of essential drugs, (2) strengthen quality control and local production of such drugs, and (3) make essential drugs available.

The WHO Expanded Programme in Immunization has developed modular course materials in Cold Chain Logistics for procurement and importation managers, storage and distribution managers, and field level users. Training workshops include practical exercises, group activities, and case studies.

UNICEF, Supply Division, 866 United Nations Plaza, Sixth Floor - Room A-6114, New York, New York 10017 U.S.A., CABLE: UNICEF, NEW YORK

Offers training at UNIPAC, the UNICEF Supply Division Packing and Assembly Centre in Copenhagen, in the methodology of inventory control, stock rotation, and quality asurance in warehouse receiving. Arranged on an individual basis, usually for personnel involved with UNICEF projects, but occasionally for non-UNICEF agencies and individuals under special agreement. Other training sometimes arranged in assessment of priority pharmaceutical needs, vehicle maintenance, and the production of oral salts according to WHO standards.

United Nations Conference on Trade and Development (UNCTAD), Technology Division, Palais des Nations, 1211 - Geneva 10, Switzerland, CABLE: UNATIONS, GENEVA

Offers seminars and training sessions to help governments formulate national drug policies -- including consideration of the issues of essential drugs, drug nomenclature, and quality assurance with regard to both imported and locally produced drugs, as well as coordination among the various ministries and institutions concerned. UNCTAD can also organize on-the-job training and exchange of personnel whereby officials of a developing country are able to spend time in a relevant organization in another country, or an expert from one country can visit another to brief officials about the experience of his organization.

United Nations Development Programme (UNDP), Division of Information, One United Nations Plaza, New York, N.Y. 10017 U.S.A., CABLE: UNDEVPOR, NEW YORK
Sponsors training in the quality control of vaccines in conjunction with the WHO Expanded Programme on Immunization. Training programs designed in collaboration with the health authorities of developing countries.

United Nations Industrial Development Organization (UNIDO), Pharmaceutical Industries Unit, Chemical Industries Section, Industrial Operations Division, Vienna International Centre, P.O. Box 300, A-1400, Vienna, Austria, CABLE: UNIDO, VIENNA
Offers seminars and training in pharmaceutical production and technology transfer. Promotes technical cooperation among developing countries.

United Nations Institute for Training and Research (UNITAR), United Nations, New York, New York 10017 U.S.A., CABLE: UNATIONS, NEW YORK
Conducts seminars in procurement and warehousing, though not specific to pharmaceuticals.

Arab Organization of Administrative Sciences, P.O. Box 1599, 8 Salah El-Din Street Zamalek, Cairo, Egypt, CABLE: MONAZAMA
Training courses and seminars in administrative sciences. Coursework in Arabic. Experts available in supply and materials management.

Asian Productivity Organization, Aoyama Dai-Ichi Mansions, 4-14 Akasaka 8-Chome, Minato-Ku, Tokyo 107 Japan, CABLE: APOFFICE
Short-term training in production management and project feasibility studies. Available only to members of the Asian Productivity Organization. Coursework in English. Fellowships available.

International Federation of Pharmaceutical Manufacturers Associations (IFPMA), P.O. Box 328 Nordstrasse 15, CH-8035 Zurich, Switzerland, CABLE: PHARMAFED ZURI
Has offered training in quality control to employees of governmental control laboratories and governmental pharmaceutical inspection services in the developing world. Training tailored to individual needs. Candidates for training to be nominated through WHO.

National and Private Organizations and Institutions

State University of Ghent, Ghent, Belgium
Six-week courses in pharmaceutical technology: production techniques (manufacturing of tablets and capsules, granulation and direct compression methods, preparation of ampules and perfusion solution, ointments), sterilization procedures, formulation of intramuscular drugs, planning for production of antibiotics, sulfonamides, antiseptics. Offered in English or French.

University of Leuven, Leuven, Belgium
Has offered courses in supply management with funding from WHO.

Ministerio de Salud Publica, 23 Y N. Vedado, La Habana, Cuba
Offers training for medical technicians in public health programs. For information write: Comision Nacional de Colaboracion Economica y Cientifico Tecnica, Calle Ira, No. 201 E A Y B, Vedado, Cuba.

PRODEC (Development Cooperation Project), Helsinki School of Economics, Runeberginkatu 22-24, SF-00100 Helsinki 10 Finland
Short-term training in import management. Coursework in English. Includes seminars, case studies, and site visits.

Empresa Nacional Portuaria, Puerto Cortes, Cortes, Honduras, CABLE: ENPORTUARIA
Exchange of scientists in the fields of port operations, receipt, inspection and handling of merchandise, and training of port workers. Direct inquiries to the attention of: Antonio Jose Coello.

Federation of Hong Kong Industries, Eldex Industrial Building, 12th Floor, Unit A, 21 Ma Tau Wei Road, Hung Hom, Kowloon, Hong Kong, CABLE: FEDINDUSTRY, HONG KONG
Offers vocational level training in packaging. Coursework in English. For information write: Hong Kong Packaging Centre, Federation of Hong Kong Industries.

Central Drug Research Institute, Chattar Manzil Palace, Post Box 173, Lucknow 226001, India, CABLE: CENDRUG
Exchange of scientists in drug technology and drug toxicity evaluation. For information, write: Council of Scientific and Industrial Research, Rafi Marg, New Delhi 110001.

Haffkine Institute, Haffkine Bio-Pharmaceutical Corporation Ltd., Acharya Donde Marg, Parel, Bombay 400 012 India, CABLE: RESEARCH
Offers vocational, technical, and graduate training in drug analysis. Coursework in English. Fellowships available. For information, write: Ministry of Education, Government of India and Health Department.
Exchange of scientists in drug research. Write: Ministry of Health and Family Planning, Government of India, New Delhi.

Indian Drugs and Pharmaceuticals Limited, N 12, NDSE, PART I, New Delhi 49, India, CABLE: INDRAPHARM
Exchange of scientists in drug research, formulation technology, formulation development, and packaging.

Institute of Port Management, New Traffic Building, 40-Circular Garden Reach Road, Calcutta 700 043, India, CABLE: HYDROSTUDY, CALCUTTA
Short-term training available in port maangement, cargo handling, materials management, and inventory control. Coursework in English.

National Institute for Training in Industrial Engineering, NITIE P.O., Vihar Lake, Bombay-400 087, India
Short-term executive level training in materials management, including forecasting, make/buy decisions, materials planning; purchasing; stores management and stock control; and inventory models. Coursework in English.

Nitson Laboratories, Road No. 22, Wagle Industrial Estate, Thana, 400604 Bombay, India
Exchange of scientists in the fields of bulk drugs process development and manufacture cost reduction.

Ranbaxy Laboratories Ltd., Okhla, New Delhi 110 020, India, CABLE: RANBAXY
Exchange of scientists in the fields of drug formulations and manufacture technology.

Suhrid Geigy Ltd., Post Box No. 47, Wadi Wadi, Baroda 390007, India, CABLE: SURIDGEIGY
Pharmaceutical technician training. Coursework in English. Address inquiries to the attention of: Sarabhai Research Centre.

UNICHEM Laboratories Limited, 4,5,6, Prabhat Estate, S V Road, Jogeshwari (West) Bombay 400 060 India, CABLE: TREATMENT BOMBAY
Vocational, technician, and graduate training in pharmaceutical management machinery operation, and quality control. Coursework in English. Exchange of scientists in pharmaceutical formulations process development.

State Organization of Iraqi Ports, Basrah, Iraq, CABLE: MAWANI
Port technician training available in Arabic.

Ministere de L'Education Nationale, Bamako, Mali
Professional and technical training in pharmacy. Coursework in French.

Instituto Mexicano de Comercio Exterior, Alfonso Reyes No. 30, Col. Condesa, Mexico 11.D F Mexico, CABLE: IMCEMEX
Technical training in quality control and packaging. Coursework in Spanish.

University of the Philippines System, College of Pharmacy, Diliman, Quezon City, Philippines
Post-secondary and university training in pharmacy, pharmaceutical chemistry, industrial pharmacy, and drugstore management. Coursework in English. Fellowships available. Exchange of scientists in pharmacy, pharmaceutical chemistry, and industrial pharmacy.

University of the Philippines System, Philippine Executive Academy, Padre Faura, Manila, Philippines
Short-term management training in transfer of technology. Coursework in English.

Port of Singapore Authority, P.O. Box 300, Singapore 1, CABLE: TANJONG, SINGAPORE
Vocational training in cargo handling techniques, port administration and operations, port technical services, and warehousing management and operations. Coursework in English. Fellowships available.

Instituto Espanol del Envase y Embalaje S.A. (IESA), Breton de los Herreros 57 Madrid 3, Spain, CABLE: EMBALAJES
Technical training in packaging. Correspondence courses, audiovisual seminars available. Courses offered in Spanish and English. Fellowships available. Address inquiries to the attention of: Dr. Luis Sicre Canut.

University of Khartoum, Faculty of Medicine, Khartoum, Sudan
Offers a course in medical storekeeping and inventory control.

National Institute for Productivity, P.O. Box 2021, Dar es Salaam, Tanzania
On-the-job management development programs in production management, management accounting, and distribution. Coursework in English.

Kampsax International A/S, 55 Oriental Avenue, Bangkok 5, Thailand
CABLE: KAMPSAX, BANGKOK

Technician training in the mechanics and operation of highway equipment, and harbor administration. Coursework in English. For information write: Kampsax International A/S, Dagmarhus 1553 Raadhuspladsen, Copenhagen, Denmark.

Institute of Production Control, 23 Wood Street, Stratford-upon-Avon, Warwicks, United Kingdom

Short-term training in materials management. Includes purchasing, requirements scheduling, ordering and stock control, inventory control, stores management, materials handling, and control of internal transport. Courses held in S -tford-upon-Avon, Edinburgh, Malta, Hong Kong, Kuala Lumpur, Singapore, Trinidad, Brazil, Stockholm, and Brussels.

Afro-American Purchasing Center, Inc., One World Trade Center, New York, New York 10048 U.S.A.

Training in international trade relations and procedures, inventory control, supply management, negotiation and contract administration, transportation and packaging, and purchasing procedures and practices. Training tailored to individual needs. Offered in English, French, or Spanish.

Center for Disease Control, Atlanta, Georgia 30333 U.S.A.

Developing for WHO a training course in oral rehydration programs, aimed at providing essential skills and knowledge to senior level public health officials who have been assigned by their governments to establish and manage national programs for the control of diarrheal disease. Modules focus on setting priority health problems, objectives, and targets; delivery systems; logistics; and evaluation.

Food and Drug Administration, Public Health Service, Department of Health and Human Services, Washington, D.C. 20201 U.S.A.

Has offered training -- both on-site and in the U.S.A. -- in quality control procedures.

Industrial Management Center, Inc., 2551 River Oak Drive, Decatur, Georgia 30033 U.S.A.

Short-term professional training in storage, warehousing, and physical distribution. Includes problem analysis, evaluation procedures, and recent developments. Coursework in English.

United States Public Health Service, Supply Service Center (Perrypoint), Office of Property Management, Department of Health and Human Services, Parklawn Building, Rockville, Maryland U.S.A.

Short-term training programs arranged *ad hoc* for developing country personnel in procurement, inventory management, receiving, accounting, storage, packaging, and quality control.

Glossary

ABC Value Analysis -- Method by which drugs are divided, according to their annual usage (unit cost times annual consumption), into Class A items (the 10 to 20 percent of the items which account for 70 to 80 percent of the funds spent), Class B items (with intermediate usage rates), and Class C items (the vast majority of items with low individual usge, the total of which accounts for less than 25 percent of the funds spent). ABC analysis can be used to give priority to Class A items in procurement, inventory control, and port-handling.

Active Ingredient -- That portion of a drug which produces the intended therapeutic effect.

Annual Purchasing -- A periodic inventory control system in which drug requirements are determined and orders are placed once each year.

Audit Trail -- The series of records and forms which compose the information system and the cross referencing of these forms which allows retracing of the flow of drugs and funds through the system. Used in evaluating system performance and in tracing losses.

Back Order -- The order for a product which is currently out of stock. These back orders are eventually satisfied when a new supply of the product becomes available.

Batch -- The quantity of drug produced in one production run.

Bid Bond -- A form of financial guarantee which is submitted when a bid is submitted. The bond is forfeited if the successful bidder withdraws his offer or refuses to agree to the announced contract requirements.

Bill of Lading -- Document certifying that the goods are in charge of the carrying vessel and dated on or before the last date for the shipment, as allowed in the letter of credit or contract. A clean bill of lading is a bill of lading signed by a common carrier acknowledging that the carrier has the materials in good order and condition without any qualifying comments. An unclean bill of lading or foul bill of lading is a bill of lading in which exceptions -- such as damaged goods, improper packaging, or other flaws -- are noted on its face.

Bin Card -- Card bearing record of receipts, issues, and balances held in the stores. The bin card is kept in the warehouse with the physical stock.

Bioavailability -- The rate and extent of absorption of a drug from its specific dosage form. This is measured by the concentration/time curve in the system circulation or by excretion in the urine.

Brand Name -- The registered trademark name given to a specific drug product by is manufacturer.

Branded Generics -- Pharmaceutical products sold under their generic name which retain a clear identification of the manufacturer on the label.

Budget -- A plan that includes an estimate of future costs and revenues arising from specific activities. These costs should be separated as operating costs or development costs.

Bulk Purchasing -- Procurement of drugs in large quantities in order to obtain lower unit prices. Generally done in a bid system in which all drugs are identified by their medical (generic, INN) name.

C.& F. (Costs and Freight) -- Same as C.I.F. except marine insurance is not included in the selling price.

C.I.F. (Cost, Insurance, Freight) -- When a seller quotes C.I.F., the price of the cost of goods, marine insurance, and all transportation charges to the named destination point are included.

Capital Cost of Inventory -- The cost of monies tied up in inventory. If average inventories increase, then capital invested in inventory increases proportionally. Since these are funds invested in inventory which could be used for other expenditures, they should be valued at current bank interest rates.

Call for Offers -- A publicized invitation to bid. Used in tender or bid purchasing. Includes product specifications, required delivery date, closing date for submitting offers, and other requirements of participation.

Card File -- A form of stock record based on the use of cards which are stored in a file box or a plastic visible-edge record tray.

Centralized Model of Orgqanization -- A system of drug supply management in which all of the major functions of the logistics system are directed by a separate pharmacy or logistics unit.

Certificate of Manufacture -- A document accompanying a commercial invoice which is presented to the buyer's bank -- usually a part of the requirements of a letter of credit -- certifying that the products have been manufactured, are ready for shipment, and are in safekeeping.

Clinical Pharmacist -- An individual trained in pharmacy, usually at the bachelor level, who has had specialized training in the uses, side effects, warnings, and dosages of medications for human use.

Clinical Pharmacologist -- A physician who has had specialized training in the use, side effects, warnings, and dosages of medications for human use.

Cold Chain -- A system of freezers, refrigerators, dry ice carriers, and other devices needed to maintain proper temperature for vaccines from the point of manufacture to the point of administration.

Combination Drug -- A pharmaceutical product containing more than one active ingredient.

Compliance -- The degree to which patients adhere to medical advice and take medicines as directed.

Component -- Resources used in the operation of a logistics system. These include administration (organizational structure, policies, procedures), an information system, personnel, facilities, equipment, finances, and drug supplies.

Compound -- To mix together the ingredients of a prescription or drug formula. Generally refers to a hand process performed for individual orders by a dispenser or pharmacist.

Consumption-Based Estimate -- Prediction of future drug requirements on the basis of historical information on drug consumption.

Contract Terms -- Specific requirements established by the buyer prior to making a supply agreement.

Cost -- Cost in drug supply systems is one of three types: drug costs, operating costs, and development costs.

Cost Accounting -- A quantitative method that accumulates, classifies, summarizes, and interprets information for the purpose of planning improvements and cost reduction.

Cost-Effectiveness -- The relationship between cost, as measured in monetary value, and effectiveness, as measured in terms of specific performance indicators. A cost-effective practice is one in which the effectiveness seems to justify the cost.

Course-of-Therapy Prepackaging -- Prepackaging of drugs in sealed plastic bags, each bag containing a complete course of treatment for that drug, as established by standard treatment norms. The package usually contains a complete label with instructions for use.

Currency -- A medium of fiscal exchange, including coins, bank notes, government notes, etc.

Decentralized Model of Organization -- A system of drug supply management in which each agency, or each facility is responsible for its own selection, procurement, storage, and use of drugs.

Demand -- The desire to purchase a product accompanied by the means of payment. Also the requirement rate of any item in terms of the quantity needed per unit of time.

Demurrage Fees -- Charges assessed by the carrier or shipping agent against the buyer for delay of a car, vessel, or vehicle beyond the time specified for unloading.

Development Costs -- Expenditures for items which are expected to have a working life more than one year. They may also be called capital costs or startup costs.

Direct Procurement -- The simplest method of procurement in which an item is purchased from a single supplier at his quoted price.

Directorate Model of Organization -- A system of drug supply management in which a separate logistics unit coordinates logistics activities, while the responsibility for performing specific functions remains decentralized.

Disintegration -- The breaking up of a tablet or capsule into granules or aggregates in an aqueous fluid.

Dispense -- To prepare and distribute to a patient a course of therapy on the basis of a prescription.

Dispenser -- An individual, usually with no more than ten years of formal education, who is trained to dispense medications, maintain stock records, and assist in procurement activities.

Dissolution -- The breaking down of fine particles into molecules or ions homogeneously dispersed in an aqueous fluid.

Distribution System -- An organization of administrative procedures, transport facilities, storage facilities, and user facilities through which supplies move from a central point to the user facilities.

Dosage Form -- The form of a completed pharmaceutical product as it is administered to a patient, for example, a tablet, oral solution, capsule, or injection.

Double-Shelf System -- A no-paperwork system for stock control in which the stock of each item is physically separated onto two shelves. When the stock on one shelf is expended, the stock from the other shelf is used, and an order for replacement stock is placed.

Drug -- Any product used in prevention or treatment, including vaccines, oral rehydration sachets, tablets, capsules, injectables, and galenicals.

Drug Formulation -- Composition of a dosage form, including the characteristics of its raw materials, and the operations required to process it.

Earnest Money -- A form of financial guarantee, like a bid bond, which is required by the buyer of the bidder at the time a bid is submitted and is forfeited if the successful bidder withdraws his offer or refuses to agree to the announced contract requirements.

Economic Order Quantity -- The amount to be purchased in a perpetual inventory system, which minimizes the cost of carrying inventory and ordering.

Economic Order Interval -- The time period between purchases in a periodic inventory system, which minimizes the cost of operating the system.

Effectiveness -- The degree to which a drug supply system provides the required services.

Efficacy -- The ability of a drug to produce scieftifically proven therapeutic effects.

Efficiency -- The extent to which effectiveness is achieved while minimizing costs.

Evaluation -- The third phase of the planning cycle in which the effects of program implementation are studied systematically.

Exchange Rate -- The rate at which currency of one country is exchanged for the currency of another country. The rate of exchange may be the Central Bank rate of exchange, the commercial rate of exchange, the free rates of exchange, or the foreign rate of exchange.

Excipient -- An inert substance used to give a pharmaceutical preparation a suitable form or consistency.

Expiration Date -- The date appearing on a drug product and established by the manufacturer, beyond which the manufacturer will not guarantee the potency, purity, uniformity, or bioavailability of the product.

External Packaging -- The case, crate, carton or other container in which individual packages are placed.

Financing -- The process of obtaining monies for a supply system and planning for the expenditure of these monies.

Financial Guarantees -- Deposits in the form of earnest money, bid bonds, peformance bonds, or retention money required of suppliers in order to guarantee their participation once they have submitted a bid or to ensure the complete fulfillment of contract obligations if the bid has been won by them.

First-In/First-Out Procedure -- A method of inventory management in which the first products received are the first products issued. This method minimizes the chance of drug expiration.

F.O.B. (Free on Board) -- A pricing strategy in which the seller bears all the costs up to the point of placing the product onboard a commercial carrier at the point of the product's origin. The buyer bears or arranges for all costs from then on.

Fixed Order Quantity System -- Another name for a perpetual inventory system.

Fixed Interval Inventory System --Another name for a periodic inventory system.

Flow Chart -- A pictorial representation of the processes and procedures for performing a specific operation.

Form -- A document which moves from one unit to another, carrying specific information about drug needs, shipments, movement of drugs, and sieilar subjects; copies are filed at various points in the distribution network to help form the "audit trail" for tracing the flow of drugs and funds.

Formulary -- A list of approved or recommended drugs compiled by an individual practitioner or a group of medical and scientific professionals for the purpose of a specific medical practice or supply system.

Freight -- The rate charged for carrying goods. The word is also applied to the items to be carried, but the correct term for them is cargo.

Functions -- In a drug supply system, the major functions are: selection, procurement, distribution, and use.

GMP (Good Manufacturing Practices) -- Performance standards for pharmaceutical manufacturers established by the World Health Organization and many national governments; include criteria for personnel, facilities, equipment, materials, manufacturing operations, labeling, packaging, quality control, and in most cases, stability testing.

Galenical -- A product prepared with one or more organic ingredient.

Gantt Chart -- One of the earliest types of project control chart designed to indicate the progress for each activity which should be made during each specific time interval.

Generic Name -- The official name of a drug, regardless of the manufacturer. The generic of "medical" name is generally the International Nonproprietary Name (INN) established by a body of the World Health Organization.

Hidden Costs -- Costs in addition to the contract price which are "hidden" in the supplier's past performance. These include costs associated with poor quality, late deliveries, defaults on deliveries, short-packing, and other factors.

Holding Costs -- The costs of carrying inventory, usually expressed as a percent of the average inventory. These include both the capital costs and the storage costs.

Identity -- Presence of the corrective active ingredient in a drug product.

Immediate Container (Package) -- The individual jar, bottle, box, blister pack, or other container in which a single group of items is packed.

Imprest System -- A form of periodic inventory control in which stocks are replenished up to a pre-established imprest level. No running stock records are kept. The only stock control document is a preprinted sheet showing each item, its description, the unit of issue, and the imprest level. Generally used at small facilities.

Information System -- The system of records which are kept at offices, storage facilities, and clinical facilities; forms which are used to communicate supply needs, consumption data, and other information about the system;

reports which summarize the data from records and forms for planning and evaluation purposes; and procedures which coordinate the use and flow of these documents.

International Procurement Services -- Organizations such as UNICEF, WHO, ECHO, and other nonprofit groups willing to assist in procurement.

Inventory -- The stock kept on hand at any point in order to protect against uncertainty, permit bulk purchasing, minimize waiting time, increase transportation efficiency, and buffer against seasonal fluctuations.

Inventory Control -- The function of supply management which aims at providing sufficient stocks of drugs at the lowest costs possible.

Inventory Models -- Systems of inventory control which determine how much stock is bought and how often it is bought. The major types are periodic and perpetual inventory systems.

Inventory Taking -- A periodic activity in which a physical count is made of the stock and compared with inventory control records.

Inventory Value -- The sum of the number of units of each item on hand or in storage in the system times the current unit price of each item.

Irrational Prescribing -- Extravagant prescribing, overprescribing, incorrect prescribing, multiple prescribing, or underprescribing of medications, as compared to good standards of treatment.

Issue -- To distribute a specific amount of an item to an intermediary stocking facility or a clinical facility.

Jobber -- A dealer who purchases supplies from a manufacturer and resells them to the ultimate buyers.

Labeling -- Placing written or symbolic instructions on the immediate container in which drugs are dispensed.

Lead Time -- The time interval needed to complete the procurement cycle. It begins at the time the need for new stock is recognized and ends when that stock is received and available for issue.

Lead Time Analysis -- A systematic study of the components of the lead time, aimed at discovering areas in which the lead time can be reduced.

Lead Time Demand -- The number of units demanded and issued during the lead time.

Letter of Credit -- An interbank document issued by the buyer's bank stating that a certain sum of money is available for the seller to claim from his bank as soon as he ships a consignment and presents the required documents as specified. The letter of credit becomes irrevocable when it is approved and numbered by the buyer's bank.

Level -- The specific location in the health system hierarchy; this may be the national, regional, district, or community level.

Level-of-Use -- A classification of drugs according to the medical practitioners who use them and the clinical facilities at which they are used.

Logistics -- The science of procuring, maintaining, and transporting supplies.

Logistics Cycle -- The recurrent sequence of functions which are required for the steady supply of goods, including selection, procurement, distribution, and use.

Make or Buy -- A management decision which involves the analysis of the cost and potential benefits of manufacturing a product, rather than buying it on the open market.

Materials Management -- The group of management functions related to the complete cycle of supply flow, including the requisitioning, purchase, storage, inventory control, shipping, and distributionof the product.

Meniscus -- The concave surface which appears at the top of a column of liquid.

Mini-Maxi Strategy -- A planning strategy which identifies the minimum changes needed to incrementally improve a system and the maximum changes needed to substantially improve the system. The costs for each alternative are specified.

Multi-Source Drug -- A drug which is available from multiple suppliers, either because it is not under patent or because the patent owner has sold licenses to other suppliers to produce the drug.

Negotiated Procurement -- A procurement method by which the buyer approaches a small number of selected potential sellers and bargains with them directly to achieve specific price or service arrangements.

Open Tender -- The formal procedure by which quotations for the supply of drugs under their medical (generic) names are invited from any manufacturer or representative on a worldwide basis, subject to the terms and conditions specified in the tender invitation.

Operating Costs -- One of three components in drug supply costs, also termed recurring costs; include all items which are routinely included in the annual operating budget.

Operational Target -- Specific goals and objectives identified by the planning process.

Order Costs -- All costs involved in placing and monitoring an order, including the cost of preparing an order, the staff time involved in routine checking of inventory levels, and any related special fees.

Order Status -- The position of an order with respect to the specific tasks which must be performed for the order to be successfully delivered to the country.

Order Quantity -- The amount of stock contracted for at any one time for any given item.

Organizational Table -- A diagram indicating the main staff positions in an organization and their relationship to each other.

Organogram -- An organizational table.

Pallet -- A transportable flat storage base, with or without sides, designed to hold and move quantities of storage by mechanical handling methods, chiefly forklift devices.

Parity Rate -- See Exchange Rate.

Patents -- Exclusive rights given manufacturers for fabrication of a specific product, use of a specific process, or application of a product or process in a specific way.

Payment Terms -- The conditions arranged between a buyer and a seller regarding the method of reimbursement. Letter of Credit and commercial or deferred terms are the most common.

Performance Bond -- A form of financial guarantee which the supplier deposits at the time he acceps the contract. This amount is forfeited if he defaults on the contract.

Periodic Inventory -- An inventory control system in which stock levels are reviewed at specific intervals and order quantities are determined on the basis of the stock on hand at the time of review.

Perpetual Inventory -- A system in which the inventory levels are continually reviewed and new orders are issued as soon as the stock falls below a predetermined reorder level.

Pharmaceutical Assistant -- One of a number of individuals trained specifically to perform some of the functions of a graduate or bachelor level pharmacist.

Pharmaceutical Product -- Any drug product used in prevention or treatment, including vaccines, oral rehydration sachets, tablets, capsules, injectables, and galenicals.

Pharmacist -- An individual who has received bachelor level training in pharmaceutical sciences, dispensing practices, industrial pharmacy, and other aspects of pharmacy.

Pharmacology -- The study of medicines and their actions.

Pharmacy Auxiliaries -- A general term used to describe pharmacy technicians, pharmaceutical assistants, prescriptionists, and dispensers, all of whom are staff members trained specifically to assist in the functions of preparing and dispensing drugs.

Pipeline -- The total of all the storage capacity which must be filled in a drug supply system, including the central medical store, regional warehouses, district warehouses, and all regional facilities.

Pipeline Analysis -- The systematic diagramming of the supply system and calculation of the amount of stock held at each point in the system. The analysis is intended to determine the amount of stock actually needed and the amount of stock held.

Planning Cycle -- The sequence by which planning, then implementation, then evaluation, then revision of plans is performed. The planning cycle which is repeated can be of constant scope in which the program does not expand, or in the form of an ever-expanding spiral, with each planning cycle concerning itself with an increasingly large program.

Planning Team -- The sum of individuals representing various interest groups assembled for the purpose of devising a framework for improving pharmaceutical supply, including an implementation plan.

Population-Based Estimate -- Prediction of future drug requirements based on the demographic composition of the population, the disease patterns, and standard norms for treatment.

Port Clearing -- The process of locating items in port, obtaining the proper import documentation, paying the necessary fees, and inspecting the drugs for damage during transit.

Potency -- The extent to which a drug contains the specified amount of the active ingredient.

Prescribing -- The act of determining what medication the patient should have and the correct dosage and duration of treatment.

Preventive Maintenance -- A series of activities performed by a mechanic and/or driver designed to prevent breakdown of vehicles. This is the least expensive form of maintenance.

Primary Manufacture -- The production of active medicinal substances and other ancillary substances from substances from basic materials, for use in pharmaceutical formulations.

Procurement -- The process of acquiring supplies, including those obtained by purchase, donation, and manufacture.

Product File -- A card or ledger file which records the performance of suppliers for each product.

Purity -- The extent to which drugs are free from potentially harmful contaminants, significant quantities of other drugs, bacteria, or other microorganisms.

Quality Assurance -- The management activities required to assure that the drug which reaches the patient is safe, effective, and acceptable to the patient.

Quality Control -- The testing of drug samples against specific standards of quality.

Receiving Report -- A document indicating when items were received, from whom, the total quantity in the shipment, and the amount of damaged or lost stock.

Record -- A document or set of documents maintained as card files, ledgers, or in folders to record specific information for use by a single unit.

Registration -- The process of requiring suppliers to file specific applications which provide detailed information, prior to considering them for an order.

Report -- A document prepared quarterly, semiannually, and/or annually to summarize drug consumption and expenditures; used to project future drug needs, to revise budgets, and to assess drug utilization.

Restricted Tender -- Procurement procedure in which participation in bidding is limited to suppliers who meet certain prerequisites or who have previously registered as suppliers.

Resistance -- The characteristic of bacteria which enables them to lose sensitivity to specific antibiotics.

Retention Money -- See Performance Bond.

Revolving Fund -- A fund for which initial capital is provided by government appropriation or bilateral donation, but which is then intended to be self-sustaining with all expenditures being replaced from monies collected for the fund.

Routing -- Determining the order in which facilities will receive their deliveries, based on the geographical location of facilities and an attempt to minimize delivery costs.

Safety Stock -- The buffer, cushion, or reserve stock kept on hand to protect against stockouts caused by delayed deliveries or markedly increased demand.

Scheduling -- Determining the dates on which one facility will deliver supplies to another.

Scheduled Purchasing -- Another name for periodic inventory control in which stock levels are reviewed at several set times and orders are placed as necessary.

Secondary Manufacture -- The processing of medicinal substances, usually together with excipients, to produce a pharmaceutical dose form.

Selection -- Systematic choice of drugs to be supplied and the amount of drugs to be supplied.

Service-Based Estimate -- Prediction of future drug requirements based on the study of health services provided, disease patterns treated, and standard treatment norms.

Service Level -- The proportion of total demand of an item which is met from stock on hand.

Shelf Life -- The length of time a material may be stored without affecting the usability, safety, purity, or potency of the item.

Single-Source Drugs -- Drugs which, because of patent rights, are available from only one manufacturer.

Specifications -- A precise description of an item to be procured, including any special requirements.

Standard Norms for Treatment -- Guidelines for therapy, usually developed by a select committee, which are used to train medical personnel and to help direct drug procurement.

Stock -- Stored goods on hand.

Stock Number -- Number designating each item in inventory. These numbers are assigned in a systematic sequence, often by therapeutic category.

Stockout -- Complete absence of an item that is normally expected to be on hand.

Stock Records -- Basic information tool for inventory management; records all transactions for an item, including receipts, issues, orders placed, orders received, and stock losses.

Stocking Cost -- The cost of maintaining stock, including the capital and storage costs.

Stock-Take -- The process of inventory taking, in which a physical count is made of all items in inventory and compared with the written record.

Storage Cost -- The costs incurred in holding inventory that are in addition to the capital costs of inventory. Storage costs include the stocking cost (floor space, taxes, utilities, etc.), deterioration and spoilage, obsolescence, expiration of products, and pilferage.

Supplier -- Any individual or company who agrees to provide medications, regardless of whether that party is the manufacturer.

Supply Management -- See Materials Management.

Supplier File -- A record kept for each individual supplier indicating when orders were placed, when they were received, what kind of service the supplier provided, and the quality of the product provided.

Supplier Reliability -- The past performance of a supplier in terms of the drug and packaging quality and level of service provided.

Symbolic Labeling -- A system for providing written instructions for patients using sketches and other graphic representations.

Tendering -- The procedure by which competing bids are entered for a particular contract.

Transshipment -- Shipment of supplies to an intermediate location, from which they are forwarded by another means of transport to a facility.

Therapeutic Equivalent -- Pharmaceutical substance which, when administered to the same individual in the same regimen, will provide essentially the same efficacy.

Therapeutic Categories -- Divisions of drugs according to their clinical use. The categories often have a system for assigning numbers.

Total Inventory Position -- All stock available and soon to be available, including stock on hand and outstanding orders.

Trade Terms -- A set of standard terms to describe the buyer's and seller's responsibilities in international trade.

Treatment Norms -- See Standard Norms for Treatment.

Two-Bin Inventory Control -- Same as Double-Shelf System except that two physically separate bins are used rather than shelves.

Unit of Issue -- The unit in which inventory is maintained. This quantity must be known whenever new issues are initiated.

Uniformity -- The characteristic of drugs by which their consistency, color, shape, and size do not vary from one dose to the next.

Use -- The process of passing drugs from the supply system to the patient, which involves labeling, packaging, dispenser training, medical auxiliary training, and physician training.

Unique Identifiers -- Techniques by which stolen or missing drugs can be identified as originating with the government supply system. Unique identifiers include labels with the program logo, recording of batch numbers, and embossing of tablets and capsules.

VEN System -- A system of setting priorities for drug purchasing and stock keeping, in which drugs are divided according to their health impact into Vital drugs, Essential drugs, and Non-essential drugs.

Visual Inventory System -- A no-paper inventory control method in which the need for order is determined simply by physically looking at the inventory on the shelf.

Wall Chart -- A method for monitoring the progress of a system, particularly for monitoring order status.

Working Stock -- That part of the inventory which fluctuates between zero and the order quantity. The other component of inventory is the Safety Stock.

Selected Annotated References

The following annotated references have been selected for their potential value as textbooks, training materials, and references for ministry of health officials, advisors, supervisors, physicians, pharmacists, and other individuals involved in the drug supply process. Recent prices, when available, have been provided to help in choosing materials for purchase. These prices do not usually include international postage and are, of course, subject to increase. A list of publishers' addresses appears at the end of the references.

A. General Works
B. Selection
C. Procurement
D. Distribution
E. Use
F. Publishers' Addresses

A. GENERAL WORKS

Bates, J.A.; Hartman, F.; O'Connor, R.W.; Quick, J.D.; and Rousselle, P.J.: Procurement and Use of Drugs: Managing the Process to Advantage. In Zatuchni, G.I. (Ed.), Vaginal Contraception: New Developments. New York: Harper and Row, 1979, pp. 325-335.

A comprehensive review of the process of selection, procurement, distribution, and use of drugs in public health programs in developing countries. Reviews some of the major logistics problems and offers a few examples of creative solutions.

Dunnill, P.: The Provision of Drugs by Appropriate Technology. Appropriate Technology 4 (2): 16-17, 1977.

Discusses the supply of pharmaceuticals in developing countries with particular emphasis on some of the aspects of pharmaceutical production. A conceptual introduction with a moderate amount of technical information.

Gish, O. and Feller, L.L.: Planning Pharmaceuticals for Primary Health Care: The Supply and Utilization of Drugs in the Third World. Washington, D.C.: American Public Health Association, International Health Programs Monograph Series, No. 2, 1979.

A detailed exposition of the issues regarding the transnational pharmaceutical industry, pharmaceutical production in developing countries, purchasing, utilization of drugs, and distribution. Heavily referenced with some scattered practical suggestions.

McMahon, R. et al: On Being in Charge--A Guide for Middle-Level Management in Primary Health Care. Geneva: World Health Organization, 1980.

Written to the mid-level manager in developing countries with liberal use of figures, summary statements, and some exercises. Covers important aspects of drug supply including selection of a formulary, stocking of drugs, record keeping, arrangement of storage space in peripheral health facilities, and some important planning aspects related to supplies movement. An excellent handbook and training guide for managers and supervisors in all types of primary health services.

National Academy of Sciences: Pharmaceuticals for Developing Countries. Washington, D.C.: Conference Proceedings, Institute of Medicine, 1979.

Proceedings of conference attended by knowledgeable persons from American governmental agencies, pharmaceutical firms, and academic institutions, and from the European pharmaceutical industry, academic science, and the World Health Organization. Papers focus on the problems associated with development and distribution of the pharmaceuticals needed by developing countries.

Reisman, A.: Materials Management for Health Services. Lexington, MA: Lexington Books, 1981. U.S.$35.95.

A somewhat technical and more advanced textbook focused primarily on hospital supply management. Extensive use of summary tables, figures, checklists, and examples to describe the functions of materials management, managerial infrastructure, audit procedures, information systems for materials management, decision rules for efficient and economical operations, and material handling equipment. Lengthy glossary.

Segall, M.: Pharmaceuticals and Health Planning in Developing Countries. Brighton, Sussex: Institute of Development Studies, Communication 119, 1975.

Basic, but comprehensive, discussion of the role of pharmaceuticals and health and health care in developing countries, therapeutic need and cost-effectiveness, national production, importation, distribution, and the process of formulating a pharmaceutical policy for a developing country. Discussion of what needs to be done, rather than how to do it.

United Nations Department of Economic and Social Affairs: Supply Management: Towards Better Use of Equipment and Material Resources in Developing Countries. New York: United Nations, No. 78.II.H.5, 1978. U.S.$4.00.

Written as a training guide for national officials and technical advisors, this 60 page monograph clearly defines and briefly explains the major components of supply management, including organization, materials procurement, shipping and transportation, inventory control, stores services,

information systems, and personnel management. Specific guidelines for staffing supply management services and a glossary are included. Not directed toward pharmaceutical supply, but an excellent introduction to supply management in general.

U.S. Department of Health, Education, and Welfare: Guidelines for Analysis of Pharmaceutical Supply System Planning. Rockville, MD: U.S. DHEW, Publication No. (PHS) 79-50086, 1979.

A somewhat academic and pro-industry, but nevertheless informative discussion of pharmaceutical sector dynamics, a conceptual framework for a pharmaceutical supply system, planning for national pharmaceutical supply policy, and some topics related to distribution of pharmaceuticals to rural populations. Relatively greater emphasis on issues which impact on the drug industry including regulation of local manufacturing, good manufacturing practices, patents, and commercial pharmacies. There is somewhat less discussion of issues related to providing drugs through public health programs and cursory discussion of practical aspects of drug logistics.

Wardell, W.M.: Controlling the Use of Therapeutic Drugs, An International Comparison. Washington, D.C.: American Enterprise Institute, 1978. U.S.$7.25.

A series of detailed country studies focused primarily on regulation of drug registration, quality, and prescription practices at the national level. Although most of the countries are developed, there are many practical ideas and realistic discussions of their implementation.

WHO: Expanded Programme on Immunization. Geneva: World Health Organization, 1977.

A comprehensive manual detailing program design, program management, vaccine handling, health education for immunization, and program evalualtion. Quite detailed, very practical, and clearly written. Very useful reference book.

World Health Organization: National Drug Policies. WHO Chronicle 29:337-349. 1975.

Outlines key points in the development of a national drug policy. Covers a range of subjects beyond those immediately relevant to public drug supply for primary health care.

Yudkin, J.: Provision of Medicines in a Developing Country. The Lancet No. 8068: 810-812, April 15, 1978.

A case study of public drug supply in an African country which highlights some of the most prevalent problems and offers a few practical interventions.

B. SELECTION
(see Appendix II.A.1. for further sources of drug information).

Bochner, F. Carruthers, G., Kampmann, J., Steiner, J., and Azarnoff, D.: Handbook of Clinical Pharmacology. Boston, MA: Little, Brown & Co., 1978. U.S.$10.95.

Handy little reference on many of the most common drugs. Does not include drugs of special interest in tropical environments.

Sewell, W.: Guide to Drug Information. Hamilton, Ill: Drug Intelligence Publications, Inc., 1976. U.S.$12.00.

Excellent comparison of numerous sources of drug information including side by side tables. Indicates the countries, languages, or areas of the world served by the source, some price information, and some side by side comparison of the content and usefulness of the information sources.

Speight, A.N.P.: Cost-Effectiveness and Drug Therapy. Tropical Doctor, 5(2), April, 1975.

A classic discussion of the problems of selecting and using drugs in a cost-effective manner in developing countries. Excellent arguments in support of rational drug use.

The Medical Letter. New Rochelle, New York: The Medical Letter, Inc.

A scientifically objective, but conservative, periodical which is available i English, Spanish, Italian, and French. Although focused priamarily on drugs of interest to American physicians, its reviews are excellent and often cover topics such as: drugs of choice for parasitic infections, use of newly released medicines, relative cost-effectiveness of alternative drugs.

UNICEF: Hygeia, 2nd Revision. New York: UNICEF, SUNO-16, May 1964.

Includes a variety of catalogue references including the names of 29 organizations with their addresses from whom clinic and ward equipment, laboratory equipment, bacteriology, serology, and biochemistry and x-ray equipment, etc. can be purchased.

UNICEF: RANI Guidelist. New York: UNICEF, 1975.

A composite list of equipment and supplies for peripheral health facilities correlated with the World Health Organization's "Provisional reference list of equipment and suplies for peripheral health services." Four types of health facilities assumed; various categories of staffing patterns are suggested.

World Health Organization: The Promotion and Development of Traditional Medicine. Geneva: World Health Organization, Technical Report Series No. 622, 1978. Annual Subscription Sw.Fr. 100.

Report of a WHO meeting in which the nature of traditional medicine, reasons for promoting traditional medicine, current utilization of traditional medicine in the national health care systems, the integration of traditional and modern medicine, and manpower development are considered. An important reference in policy discussions concerning the inclusion of traditional medicine in public health programs.

World Health Organization:. The Selection of Essential Drugs. Geneva: World Health Organization, Technical Report Series No. 615, 1977. Annual Subscription Sw.Fr. 100.

A comprehensive discussion of the process by which the WHO essential drug list was developed and a clear listing of the guidelines which countries should use in developing their own drug lists.

World Health Organization: The Selection of Essential Drugs. Geneva: World Health Organization, Technical Report Series No. 641, 1979. Annual Subscription Sw.Fr. 100.

Does not include a discussion of the process for selecting essential drugs, but has a lengthier list than the original report and provides a therapeutic classification for these drugs.

World Health Organization: Drug Information. Geneva, World Health Organization, PDT/DI.

A bulletin devoted to international transfer of information on current drug problems. Published quarterly. Availale free.

C. PROCUREMENT

Aljian, G.W.: Purchasing Handbook. New York: McGraw-Hill Book Company, 1973. U.S.$45.95.

Standard reference book on policies, practices, and procedures utilized in departments responsible for purchasing management or materials management. Lists professional purchasing organizations on pages 29-7 to 29-12. For advanced personnel.

American Hospital Association: Medical Equipment Management in Hospitals. Illinois: American Hospital Association, 1978. U.S.$45.00.

Useful work appropriate for large sophisticated hospitals.

Ammer, D.S.: Purchasing and Materials Management for Health Care Institutions. Lexington, MA: D.C. Heath and Co., 1975. U.S.$15.95.

A very clearly written introduction to most aspects of procurement and materials management as they relate to health care organizations. Although written for developed countries, the content is largely applicable in any health organization. Discusses quality assurance, make-buy decisions, purchasing mechanisms, techniques of cost reduction, basic principles of inventory management, and measuring performance of purchasing organizations. Excellent basic text.

Baily, P.J.H.: Purchasing and Supply Management, London: Chapman and Hall, 1978. U.S.$19.95.

Very readable paperback with content somewhat similar to the Ammer book, but greater emphasis on large scale institutional purchasing and somewhat less emphasis on materials management within the institution. Valuable introductory text and reference.

Combs, P.H.: Handbook of International Purchasing, 2nd Edition. Boston: C.B.I. Publishing, 1976. U.S.$14.95.

Basic description of the mechanisms of international purchasing with emphasis on commercial entreprises. Contains basic definitions, explanations of international trade terms and forms, and some principles of economical procurement.

Gasdia, S.D. and Brennan, E.C.: Purchasing Pharmaceuticals on a Competitive Basis. Hospital Formulary Management, August-September, 1968.

Focuses specifically on bid purchasing of pharmaceuticals and provides some very practical guidelines on quality control, supplier selection, and other pertinent topics.

UNIDO: The Growth of the Pharmaceutical Industry in Developing Countries: Problems and Prospects. New York: United Nations Sales No.: E.78.II.B.4., 1978. U.S.$2.50.

Provides useful background on the magnitude of production, trade dynamics, marketing patterns, and drug innovation among multinational pharmaceutical companies. Then explores issues of importation, production, marketing, and distribution as they apply to the promotion of pharmaceutical production capacity in developing countries. Considers several new policies on pharmaceuticals, including the preparation of a priority drug list, national drug-buying agencies, local research and development, joint action through proposed Co-operative Pharmaceutical Production and Technology Centres (COPPTECs), and the role of UNIDO in the field of pharmaceuticals.

UNIDO: Information Sources on the Pharmaceutical Industry. New York: United Nations Industrial Development Organization, 1976.

Bibliographic reference which is of some use if course-of-therapy packaging is being considered.

UNIDO: Manual for the Preparation of Industrial Feasibility Studies. New York: United Nations Industrial Development Organization, 1978.

A rather technical, but complete guide to the preparation of the type of study necessary to evaluate the wisdom of initiating local or government production. Worth having if local production is being planned.

UNIDO: Appropriate Industrial Technology for Drugs and Pharmaceuticals. New York: United Nations Industrial Development Organization, 1980.

Contains some discussion of the principles involved in establishing domestic pharmaceutical production and gives a number of enlightening country studies. Should be read by those considering government or local production.

U.S. Department of Health, Education, and Welfare: Guidelines for Analysis of Health Sector Financing in Developing Countries. International Health Planning Methods Series. DHEW Publication No. (PHS) 79-50087, 1979.

General discussion of health sector components and costs, sources of data on health sector financing, and issues in evaluating the impact of financing strategies. Includes some useful sample tables for analyses and an extensive bibliography. A thought provoking starting place for policy discussions on financing alternatives.

Westring, G.: International Procurement: A Training Manual. New York: United Nations Institute for Training and Research, 1977.

A very dense text book which is not particularly oriented to supplies procurement and certainly not to pharmaceuticals procurement. Nevertheless provides some detailed discussions on some of the fundamental aspects of purchasing including trade terms, procurement methods, techniques for quality assurance and purchasing, and payment mechanisms.

WHO: Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. Geneva: World Health Organization, 1978.

WHO scheme provides a feasible but largely untested means of quality assurance for international purchasers. The publication describes a process for obtaining certification from these suppliers' national drug regulatory agency and gives a sample form which can be used for this purpose.

D. DISTRIBUTION

Attwood, P.R.: Planning a Distribution System. London: Gower Press Limited, 1971.

Textbook aimed primarily at commercial entreprises in developed countries. Provides a systematic discussion of the process involved in designing or redesigning a distribution system. Will not solve the problem of spare parts or bad roads, but will provide some guidance for optimizing the use of available resources.

Blake, M.I.: Shelf-Life and Storage Conditions. American Druggist 175:30, 84, (May), 1977.

Useful pointers regarding storage and labeling of drugs.

Bowersox, D.J.: Logistical Management: A System Integration of Physical Distribution Management and Materials Management. New York: Macmillan Publishing Co., Inc., 1974. U.S.$19.95.

Comprehensive discussion of all aspects of logistics. Although based on the commercial sector its discussion of physical distribution, materials managemen coordination, planning, transportation, inventory control, warehousing, system design, and administration will be useful for individuals not trained in logistics management. For more advanced training and personnel.

Drug and Therapeutics Bulletin (Editorial): Storage and Shelf-Life of Drugs: When is it important? Drug and Therapeutics Bulletin 15 (21): 81-83, 1977.

One of these few discussions of when and why worry about shelf life. Not particularly good for the purposes of drug supply in public health programs but is a reasonable introduction.

Elford, J.: How to Look After a Refrigerator. London: AHRTAG, 1980. U.S.$11.00 (includes air mail postage).

Clear and simple step-by-step instructions for the care and maintenance of kerosene, gas, and electric refrigerators. Also describes how to store vaccines safely in the refrigerator, cold boxes, and vaccine carriers. A must for cold chain maintenance.

England, R.: How to Make Basic Hospital Equipment. London: Intermediate Technology Publications, Ltd., 1980.

The late Will Eaves, a medical engineer, designed and built beds, wheelchairs, metal tubing and other equipment from wood, metal tubing, and wheels taken from scrap heaps in Africa. This book brings together Eaves' designs as well as those of other health workers in various parts of the world.

Intermediate Technology: A Manual on Building Construction. London: Intermediate Technology Publications, Ltd., 1975.

A general and practical manual which considers design issues and business details, as well as instruction in masonry, carpentry, concrete, and finishing trades. Some parts useful for warehouses and storage facilities.

Lloyd, John S.: Improving the Cold Chain for Vaccines. Who Chronicle, Vol. 31, No. 1, January 1977.

A clear, concise, but fairly comprehensive review of the main technical and management issues in the operation of an effective vaccine cold chain. Discusses typical problems and describes the cold chain from vaccines manufacture to mobile field vaccination teams. Emphasis on local production. Based on experiences in Ghana, but has general applicability.

Oates, J.: Maintaining your Car. New York: Laubach Literacy International, 1979.

This manual, with its easy to follow instructions, makes simple repairs easy. The book's clear illustrations can help make simple repairs or spot a system that isn't working properly. Fuel, engine, ignition, exhaust, electrical, cooling, lubrication, suspension, steering and braking are all explained, as are the systems' common ailments and their symptoms.

Taff, C.A.: Management of Physical Distribution and Transportation. Homewood, Ill.: Richard D. Irwin, Inc., 1972. U.S.$18.95.

A basic textbook with many of the topics covered in Bowersox. It has some helpful discussion of warehouse management, make-buy decisions, packaging, and international distribution. Also covers documentation and shipper liability. Medium-level text for knowledgeable personnel.

WHO Expanded Programme on Immunization: Training for Mid-level Managers. Geneva: World Health Organization, 1979.

A step by step discussion of all aspects of the organization, management, and operations of vaccine supply programs. It provides many practical suggestions and specific guidelines for managers at all levels of the supply system. Training models include: Allocate resources, Manage the Cold Chain System, Conduct Vaccination Sessions, Supervise Performance, Provide Training, Conduct Disease Surveillance, and Ensure Public Participation. Well worth having.

E. USE
(see Appendix II.A.1. for additional references on drug prescribing and use.)

American Society of Hospital Pharmacists: Training Guidelines for Hospital Pharmacy Supportive Personnel. Washington, D.C.: American Society of Hospital Pharmacists, 1976.

Aimed at western hospitals, but provides a good format for evaluating pharmacy support personnel, and it is cheap.

Blum, R., Herxheimer, A., Stenzlaed, C., Woodcock,J. (Eds.): Pharmaceuticals and Health Policy. New York: Holmes and Meier, 1981. U.S.$37.50, 272 pp.

Comprehensive and highly useful volume. Addresses some of the medical issues and data bearing on the major aspects of drug supply, beginning with research in the laboratory, going through manufacture, with drug evaluation, marketing, then through education of prescribers and dispensers, and finally to the central figure, the consuming patient.

Bowler, D.P.: Child Health Manual for Community Nurses. Geneva: World Health Organization in conjunction with the Department of Health, Papua New Guinea, 1973. 159 pp.

Covers most aspects of child health care, and includes a section on maternal health. Basic nursing knowledge is assumed. Symptoms, diagnosis, treatment, and drugs are dealt with in the relevant sections. Very useful, and applicable to auxiliaries in other regions. Available in English and French; Portuguese version in preparation.

Chesterman, C.C.: Tropical Dispensary Handbook. Guildford, United Kingdom: Lutterworth Press, 1960.

An aid to the training and practice of medical assistants, in regard to those involved in medical practice for rural dispensaries in developing countries.

Durgin, J.M., Hanan, Z.I., and Ward, C.O.: Pharmacy Technicians' Manual, Second Edition. St. Louis, The C.V. Mosby Company, 1978. U.S.$15.50.

A handy text book for the training of pharmacy technicians, dispensers, and compounders in general aspects of pharmacy, purchasing, inventory control, dosage forms, dispensing systems, drug information, and the role of the technician.

Elliott, K.: Auxiliaries in Primary Health Care: An Annotated Bibliography. London: Intermediate Technology Publications, Ltd., 1979.

Valuable reference for all those concerned with the training and supervision of health auxiliaries. Presents different approaches being used to integrate auxiliary health workers into existing health systems. Some coverage of drugs

Fendall, N.R.E.: Auxiliaries in Primary Medical Care: Programs in Developing Countries. Chapter X, Pharmacy and the Auxiliary. Baltimore, MD: Johns Hopkins Press, 1972.

Detailed description of pharmacy auxiliaries in various developing countries with some practical examples.

Goarnisson, J. and Blanc, C.: Guide Medical Africain, Medicine Tropicale. Issy-les-Moulieaux, France: Editions Saint Paul, 1972, 743 pp.

Suitable for use as a manual for medical assistants. Deals with illnesses common to tropical countries, particularly in Africa, and indicates causes, symptoms, and treatment for each disease. It also covers the examination of the patient, medical and surgical techniques, emergency cases, skin diseases, child pathology, etc. Several illustrations and a subject index are included.

Jelliffe, D.B.: Child Health in the Tropics. London: Edward Arnold, 1974. 170 pp.

Practical and simple book intended for use by medical and paramedical personnel, and particularly by their teachers. It covers the clinical, preventive and social aspects of child health in the tropics. Contains a useful list of pediatric drug dosages, a suggested schedule of immunization, a valuable bibliography, and an index. Illustrated with line drawings.

Mtulia, I.A.T.: Pharmacology & Therapuetics. Nairobi, Kenya: African Medical and Research Foundation, Rural Health Series 5, 1976.

A standard therapeutics manual for medical assistants and rural medical workers, which covers basic definitions, basic pharmacology, dose forms, therapeutic principles, cost-considerations. Laid out like a standard reference book with the action, indication, available preparations, toxic effects, and other side effects of drugs commonly used in tropical countries.

World Health Organization: Equipment for Vector Control. Geneva: World Health Organization, 1974. U.S.$9.60.

Useful practical handbook detailing principles of pesticide application, use of ground equipment and aircraft in vector control, and the various specifications desirable for equipment. Available in French and Spanish.

World Health Organization: Reference Material for Health Auxiliaries and Their Teachers. Geneva: WHO Offset Pulication No. 28, 1976. Sw.Fr.15.

Annotated bibliography of reference materials to help in preparing locally adapted manuals and other educational materials for health auxiliaries. Items listed according to subject; publishers' addresses included. In English and French.

Wyatt, G.B. and Wyatt, J.L.: Medical Assistant's Manual. Berkshire, United Kingdom: McGraw-Hill International Health Services Series, 1973.

A therapeutics manual aimed at physicians and medical assistants in tropical countries. Fairly current and quite useful.

F. PUBLISHERS' ADDRESSES

African Medical and Research Foundation
P.O. Box 30125
Nairobi, Kenya

American Enterprise Institute for
Public Policy Research (AEI)
1150 17th Street, N.W.
Washington, D.C. 20036
U.S.A.

American Hospital Association
840 N. Lake Shore Drive
Chicago, Illinois 60611
U.S.A.

American Public Health Association
1015 Eighteenth Street, N.W.
Washington, D.C. 20036
U.S.A.

American Society of Hospital
Pharmacists
4630 Montgomery Avenue
Washington, D.C. 20014
U.S.A.

Appropriate Health Resources and
Technologies Action Grop (AHRTAG)
85 Marylebone High Street
London W1M 3DE
United Kingdom

Appropriate Technology
9 King Street
London WC2E 8HN
United Kingdom

C.V. Mosby Company, Ltd.
11830 Westline Industrial Dr.
St. Louis, Missouri 63141
U.S.A.

Hospital Formulary Management
Modern Medicine Publications, Inc.
(Div. of Harcourt Brace Jovanovich)
1 East 1st Street
Duluth, Minnesota 55802
U.S.A.

Institute of Development Studies
University of Sussex
Andrew Cohen Building
Falmer
Brighton, Sussex, BN1 9RE
United Kingdom

Intermediate Technology Pulications, L
9 King Street
London WC2E 8HN
United Kingdom

Johns Hopkins Press
34th and Charles Street
Baltimore, Maryland 21218
U.S.A.

The Lancet
7 Adam Street
Adelphi
London WC2
United Kingdom

Laubach Literacy International
Box 131
Syracuse, New York 13210
U.S.A.

Lexington Books
D.C. Heath and Company
125 Spring Street
Lexington, Massachusetts 02173
U.S.A.

Little, Brown and Co.
34 Beacon Street
Boston, Massachusetts 02106
U.S.A.

Lutterworth Press
Luke House
Farnham Road
Guildford, Surrey GU1 4XD
United Kingdom

C.B.I. Publishing
51 Sleeper Street
Boston, Massachusetts 02210
U.S.A.

Chapman and Hall, Ltd.
11 New Fetter Lane
London EC4
United Kingdom

D.C. Heath and Company
125 Spring Street
Lexington, Massachusetts 02173
U.S.A.

Drug Intelligence Publications
Hamilton Press
1241 Broadway
Hamilton, Illinois 62341
U.S.A.

Drug and Therapeutics Bulletin
Consumers' Association
14 Buckingham Street
London WC2 N6DS
United Kingdom

Editions Saint Paul
184, Avenue de Verdun
92130 Issy-les-Moulineaux
France

Edward Arnold Ltd.
125 Hill Street
London W1
United Kingdom

Gower Publishing Company, Ltd.
20 Endell Street
London WC2
United Kingdom

Harper and Row Publishers, Inc..
10 East 53rd Street
New York, New York 10022
U.S.A.

Holmes and Meier
30 Irving Place
New York, New York 10003
U.S.A.

Macmillan Publishing Co., Inc.
866 3rd Avenue
New York, New York 10022
U.S.A.

McGraw-Hill Book Company
1221 Avenue of the Americas
New York, New York 10020
U.S.A.

McGraw-Hill International Publications
34 Dover Street
London W1
United Kingdom

The Medical Letter, Inc.
56 Harrison Street
New Rochelle, New York 10801
U.S.A.

National Academy of Sciences
Institute of Medicine
Office of Information
2101 Constitution Avenue
Washington, D.C. 20418
U.S.A.

Richard D. Irwin, Inc.
1818 Ridge Road
Homewood, Illinois 60430
U.S.A.

Tropical Doctor
Royal Society of Medicine
Chandos House
2 Queen Anne Street
London W1M 0BR
United Kingdom

United Nations
United Nations Plaza
New York, New York 10009
U.S.A.

UNICEF
United Nations Plaza
New York, New York 10009
U.S.A.

United Nations Industrial
Development Organization
Felderhaus, Rathausplatz 2
A-1010 Vienna
Austria

United Nations Institute for
Training and Research
United Nations Plaza
New York, New York 10009
U.S.A.

U.S. Department of Health,
Education and Welfare
Office of International Health
Division of Professional Resources
330 Independence Avenue, S.W.
Washington, D.C. 20201
U.S.A.

World Health Organization
Avenue Appia
1211 Geneva 27
Switzerland

WHO Chronicle
World Health Organization
Avenue Appia
1211 Geneva 27
Switzerland

About MSH, the Editors, and the Contributors

About Management Sciences for Health

Management Sciences for Health (MSH) was established in 1971 as an independent foundation that works worldwide to promote the practical application of management techniques in public health and to increase skills and knowledge in these areas. Internationally, MSH has worked with host governments on the development and implementation of health services in more than thirty countries in Asia, Africa, and Latin America, often sponsored by international and bilateral donor agencies or directly by the host-country institutions. Assistance in the management of drug supply has included efforts to develop national formularies, improve procurement systems to achieve quality assurance and low prices, improve distribution strategies, develop packaging and labeling systems, and promote community pharmacies.

Domestically, MSH is involved in the development, testing, and implementation of consumer-health-education strategies for personal health promotion in school, community, and workplace settings. The multinational professional staff of MSH includes specialists in management, operations research, medicine, public health, statistics, epidemiology, education, and computer and social sciences.

About the Editors

Jonathan D. Quick is a family physician with experience in pharmaceutical logistics, health services research, and health policy. He received his undergraduate degree at Harvard University and his medical degree from the University of Rochester. He also holds a master's degree in Preventive Medicine and Community Health. In 1978, under a technical services agreement with the World Health Organization, he traveled for Management Sciences for Health to South America, Scandinavia, Africa, Asia, and the Western Pacific to study pharmaceutical services in public programs. He has served as a short-term consultant to MSH on pharmaceutical logistics and training programs for medical supply personnel. He has published articles on preventive management, maternal and child health, and management science. Currently, he is Chief Resident in Family Medicine at Duke University Medical Center.

Margaret L. Hume is a project associate at Management Sciences for Health, with experience in public health management and program evaluation. She holds a master's degree from Harvard University, School of Public Health. At MSH, she has functioned as project manager in the preparation of Managing Drug Supply; has coauthored a report on pharmaceutical logistics training opportunities available to public health personnel in developing countries; and has

served as evaluator and dissemination manager for the MSH health/nutrition education programs. Prior to joining MSH, Ms. Hume spent two years in Ivory Coast, West Africa, as a rural development advisor and educator.

Ronald W. O'Connor is the President and founder of Management Sciences for Health. He was graduated from Yale University, and received his medical degree from the College of Physicians and Surgeons, Columbia University; he also holds master's degrees in public health from Harvard University and in management from the Massachusetts Institute of Technology. At MSH Dr. O'Connor directs several international health projects. He has had primary responsibility for worldwide projects in family planning and the development of information systems for project management and evaluation. He has served as a consultant to many international organizations and USAID in the design of logistics systems and curriculum development. He is the senior author of Managing Health Systems in Developing Areas: Experiences from Afghanistan. Dr. O'Connor also directs MSH's community and school-based health education programs.

About the Contributors

James A. Bates is the Logistics System Advisor to the Ministry of Health in Haiti, as a member of the Management Sciences for Health technical assistance team. Mr. Bates holds a master's degree in History from the University of Wisconsin. Prior to his work in Haiti, he has been a consultant to MSH in Afghanistan, Bolivia, Peru, and Honduras, where he has been involved in the design and evaluation of the supply components of rural health systems, the development of operations manuals, and the improvement of systems for forecasting, budgeting, procurement, storage, delivery, and effective use of medical supplies.

Henk W.A. den Besten is the Director of the International Dispensary Association (IDA) foundation on logistics and special projects (Amsterdam, The Netherlands). He holds two master's degrees, one in civil engineering from the Delft Technical School and another in business administration from the Delft Business School. He joined IDA in 1979, first as a staff member in logistics and later as interim general manager responsible for policy, planning, and international distribution of pharmaceuticals. He became Director in 1980. Mr. den Besten has also been a consultant to a number of international development organizations.

Peter Cross has extensive experience in issues of drug supply in developing countries. He worked for four years in Afghanistan, devoting much time and effort to drug supply and use at the Basic Health Center and Village Health Worker levels of the rural health system. He was responsible for developing the course-of-therapy packaging operation that supported the Village Health

Worker program, including the material and financial accounting systems. Since leaving Afghanistan in 1979, he has worked on the drug supply problems of public health programs in Burma, Nepal, North Yemen, Guinea-Bissau, Honduras, Haiti, and Peru. Mr. Cross was educated at the California Institute of Technology and did doctoral work at the Graduate School of Public and International Affairs at the University of Pittsburgh.

Vimal Dias is a Management Consultant at the National Institute of Management in Sri Lanka. In that capacity he has been a long-term advisor to the State Pharmaceuticals Corporation (SPC), the largest importer and distributor of pharmaceuticals in Sri Lanka. His work for the SPC has involved the design and implementation of systems for forecasting drug requirements, inventory control, stores management, and merit rating of suppliers. The policies and practices adopted by the SPC, under Mr. Dias' guidance, have since been published as case studies by UNCTAD. Mr. Dias holds a master's degree in Industrial Engineering and Management from Columbia University.

A. Frederick Hartman is a staff associate at Management Sciences for Health, and Director of MSH Programs in Latin America. He holds an M.D. and a master's degree in public health planning and administration. His work in several Latin American countries has included rural health planning; health sector analysis in the areas of primary health care, administration, finance, human resources, and logistics; the design of information and evaluation systems; and the design of pharmaceutical logistics systems. He is first author of an MSH report on pharmaceutical logistics training opportunities available to public health personnel in developing countries. Before joining MSH, Dr. Hartman served as the Medical Director of a major rural health project in the Central Amazon of Brazil, and as epidemiologist in the WHO Smallpox Eradication Program in India.

William Hewitt is a Registered Pharmacist and Chartered Chemist with the Pharmaceutical Production Consultancy (Birmingham, England). He studied pharmacy at the University of Nottingham and chemistry at Chelsea College of Science and Technology, London. His experience has included work in pharmaceutical quality control, particularly the microbiological potency testing of antibiotics, training of pharmaceutical inspectors, and feasibility studies on pharmaceutical manufacture. He has been a consultant to the World Health Organization, other international organizations, and numerous individual countries.

Aida A. LeRoy is Chief Executive Officer of Health Information Designs, Inc. (Washington, D.C.). She holds a Doctor of Pharmacy degree from the University of California, San Francisco Medical Center, School of Pharmcy. Dr. LeRoy's experience includes health program research, design, and implementation; the analysis and design of pharmaceutical logistics programs; clinical pharmacy and drug epidemiology studies; and drug utilization review. She has worked in

many countries in Latin America to develop a drug selection model, to produce a therapeutically oriented drug formulary with level-of-care designations, and to analyze drug procurement policies. Dr. LeRoy also serves as a consultant to the Pan American Health Organization on pharmaceutical issues.

M. Lee Morse is President of Health Information Designs, Inc. (Washington, D.C.), where he directs the firm's research, system design, and economic evaluation projects. His areas of expertise include pharmaceutical systems research, management information system (health care) design, statistical protocols, cost-benefit analysis, and economic impact evaluation. Mr. Morse holds a faculty appointment as Assistant Professor of Pharmacy Practice at Howard University. He has been a consultant to the U.S. Food and Drug Administration, three State Medicaid programs, Harvard Medical School, the University of Maryland School of Pharmacy, and the Pan American Health Organization.

Peter Rousselle is the Vice-President in charge of International Programs at Management Sciences for Health. He holds a degree in management from the Massachusetts Institute of Technology. At MSH, he supervises all international projects. He has worked on a long-term basis in Jamaica, India, Korea, and the Philippines, and for shorter periods in many other countries. His work has focused on the application of management techniques and concepts to the planning, inplementation, and evaluation of developing country public health programs.

Michael Prokosch began doing lettering and design professionally in 1970, upon graduating from college. Since that time he has also worked as a film critic, industrial filmmaker, newspaper editor and manager, advertising salesperson, stripper, typesetter, illustrator, and designer of books and bookcovers, brochures, posters, and newspapers.

Problem Index

This Index is to help readers find specific sources of information and guidance in the manual. Although problems, causes, and corrective actions are described indivdually here, there are few pitfalls in drug supply systems which are amenable to isolated interventions in one area. Lasting, substantive improvements are based on a comprehensive approach to the supply system. Nevertheless, this Index may be a useful starting place for action in some programs.

PROBLEM Possible Causes	Corrective Actions	Reference in Manual*
1. SHORTAGES AND STOCKOUTS ARE COMMON.		
a. At All Facilities		
• Buying unnecessary, duplicate, or extravagant drugs leaves too little money for basic drugs.	• Formalize the selection process and set specific selection criteria. • Emphasize pharmacology and therapeutics in medical training.	II.A.2. II.A.3. V.A.2.a.
• Hospital demand for special drugs takes funds from basic drugs.	• Organize formulary by Level-of-Use categories; distribute by category. • Classify drug list by VEN system and health impact of drugs and use this for procurement priorities.	II.A.3.f. VI.B.2.
• Too much of some medicines, too little of others.	• Use a systematic method of predicting drug needs. • Develop reliable consumption information through inventory control systems.	II.B.2. IV.B.2.
• Money wasted on too much of some items because order size based on bribes.	• Use committee structure to review order quantities, drug selections. • Use formal method to determine order quantities. • Improve security system.	III.C.4. VI.C.2. II.B.2. IV.B.2. VI.C.2.

*Chapter and sub-section.

PROBLEM Possible Causes	Corrective Actions	Reference in Manual
• Staff does not anticipate needs and under-estimates delivery time.	• Stengthen inventory control. • Routinely supervise staff activities. • Perform lead time analysis. • Train staff for drug supply activities.	IV.B.2. VI.A.3.c. VI.B.4. VI.D.
• No emergency stocks of basic drugs for use during epidemics and when deliveries are late.	• Systematically determine working stock and safety stock levels. • Set safety stocks by health impact of drugs (VEN System)	IV.B.1. VI.B.2.
• Drugs damaged or destroyed in shipment because of shoddy packaging.	• Specify packaging requirements in contract. • Carefully inspect drug receipts to assure supplier compliance with packaging requirements. • Maintain supplier file for merit rating and exclude those with inadequate packaging.	III.B.2. IV.D.3. III.C.3.
• Drugs stolen from port, warehouses, vehicles, etc.	• Use proper materials handling procedures. • Specify unique identifiers in supplier contracts to facilitate identification of stolen goods. • Devote increased efforts and resources to building adequate security system. • Strengthen inventory control system to provide audit trail for losses.	IV.D.4. VI.C.2.a. VI.C.2. IV.B.1.
b. <u>At Central Medical Stores</u>		
• Suppliers fail to deliver.	• Select suppliers carefully; use a merit rating system. • Require security deposit or performance bond.	III.C.3.b. III.B.2.g.
• Supplies arrive late.	• Maintain supplier file and exclude those who are chronically late.	III.C.3.b.

PROBLEM Possible Causes	Corrective Actions	Reference in Manual
	• Require security deposit and reduce the ultimate payment for late delivery.	III.B.2.g.
	• Perform lead time analysis to determine where lead time can be reduced.	VI.B.4.
	• Monitor order status closely and pressure suppliers who are late.	III.B.3.
• Drugs delayed in port, which leads to damage and theft.	• Use an order monitoring system to anticipate exact date and vessel drugs will arrive on.	III.B.3.
	• Use a port activity monitoring system to expedite port-clearing process.	IV.C.2.
	• Negotiate special port-clearing procedures to expedite drug shipment clearance.	IV.C.4.
	• Use local agents to facilitate the process.	III.C.5. IV.C.4.
	• Make supplier accountable financially for delays and expenses due to his failure to provide documents.	III.B.2.g.
• Supplies and money run out in the middle of the year.	• Use formal system for reconciling needs and funds prior to initiating purchases.	II.B.3.d.
	• Use a priority system (e.g., VEN) to assure that basic drugs will be available continuously.	VI.B.2.
c. <u>At Regional and District Facilities</u>		
• Not enough supplies at central medical stores to supply facilities	• (specific problems and corrective actions noted above)	
• Not enough of some items ordered	• Strengthen inventory control procedures.	IV.B.1.
	• Train staff in supply management techniques.	VI.D.

PROBLEM Possible Causes	Corrective Actions	Reference in Manual
• Deliveries take too long.	• Route and schedule vehicles and other transport systematically.	IV.E.3.
• Too many "emergency deliveries" take up vehicles, preventing routine deliveries.	• Improve inventory control and requisitioning practices. • Improve vehicle scheduling and routing.	IV.B.1. IV.E.3.
• Vehicle breakdowns prevent deliveries.	• Use preventive approach to vehicle maintenance, driver training, and vehicle selection. • Devise system to make spare parts available.	IV.E.2. IV.E.2.e.
• Drugs stolen or damaged in transit.	• Strengthen security system. • Set strict packaging requirements for suppliers and enforce these requirements.	VI.C.2. III.B.2.j. IV.D.3.
d. At Health Centers and Dispensaries, and for Community Health Workers		
• The delivery system fails.	• (specific problems and corrective actions noted above)	
• Supplies don't get to remote places.	• Use comprehensive, creative approach to delivery strategies. • "Piggyback" on available commercial distribution networks where possible. • Institute system of regional stores.	IV.E.1. IV.E.1.c. IV.D.1.
• Stocks of certain items build up at some facilities, while other facilities need them.	• Develop system for redistributing stock. • Use inventory control procedures appropriate to staff capabilities and needs, possibly the Imprest System.	VI.B.5. IV.B.5.
• Drugs expire before they are used -- sometimes before they arrive.	• Establish clear policy regarding expiration dates; some products may be used after the stated expiration date.	III.D.1.

PROBLEM Possible Causes	Corrective Actions	Reference in Manual
	• Institute and encourage procedures to rotate stock, monitor expiration dates, and in other ways reduce drug expiration.	VI.B.5.
	• Specify required shelf-lives in the supply contract; inspect drug shipments for adherence to these dates.	III.B.2.k. IV.D.3.
• Rainy season disrupts supply.	• Adjust safety stocks on a seasonal basis.	IV.B.1.c.
	• Plan delivery schedule to stock before rainy season.	IV.E.3.
• Never enough supplies for epidemics.	• Keep safety stocks of emergency drugs.	IV.B.1.c.
	• Adjust safety stocks by health impact of drugs (VEN System).	VI.B.2.
2. DRUGS SEEM TOO COSTLY.		
• Not enough money.	• Explore other funding options from bilateral aid, government sources, non-government sources.	III.E.3.
	• Institute system of charging small fees for drugs (Drug Sales Program).	III.E.4.
• Prices too high.	• Institute a system of open or restricted bids (tenders).	III.B.1.
	• Hire and train experienced, knowledgeable procurement staff.	VI.A.3. VI.D.
	• Publicize Calls for Offers widely and allow sufficient time for submission of offers.	III.C.2.
	• Expand the role of participating suppliers without enlisting poor quality suppliers.	III.C.2.
• Expensive brand name drugs bought.	• Review differences between brand name and generic name products. Procure by generic name only, unless specific exceptions are justified.	II.A.3.b.

PROBLEM Possible Causes	Corrective Actions	Reference in Manual
	• Use comprehensive quality assurance techniques, rather than brand name, to maintain drug quality.	III.D.2.
• Bribery and fraud raise prices.	• Use committee structure to select suppliers. • Strengthen security system.	III.C.4. VI.C.2.
• High dependence on costly imports.	• Consider feasibility of local production; build capacity gradually as experience and staff capability allow.	III.F.
• High prices paid for "panic buying" and high airfreight fees to prevent stockouts.	• Improve inventory control and forecasting procedures; make inventory control system more responsive to rapid changes in demand.	II.B.2. IV.B.1.
• High inventories of some items waste limited funds.	• Systematically reduce safety stocks and working stocks with management techniques such as ABC value analysis, VEN system (classification of drugs by health impact). • Procure smaller quantities of drugs more frequently.	VI.B.2. VI.B.3. IV.B.1.
3. DRUGS ARE OF POOR QUALITY WHEN THEY GET TO THE PATIENT.		
• Supplier makes a shoddy product.	• Select suppliers more carefully; use merit rating of supplier performance. • Institute comprehensive quality assurance program. • Use WHO Certification Scheme, other international resources to check supplier quality.	III.C.3. III.D.3. III.D.3.
• Supplier fraud or negligence.	• Require security deposit to discourage overt fraud. • Carefully inspect drug shipments to uncover overtly shoddy products.	III.B.2.g. IV.D.3.
• Rapid deterioration because of bad storage and transport conditions.	• Establish and maintain adequate storage.	IV.D.4.

PROBLEM Possible Causes	Corrective Actions	Reference in Manual
	• Train and supervise storemen in supply handling.	IV.D.4. VI.D.
• Drugs expire before being given to patients.	• (specific problems and corrective actions noted in 1.d., above)	
• Cold chain breakdowns go unnoticed or are ignored, resulting in weak or impotent vaccines being used.	• Maintain adequate cold chain equipment, procedures, and record-keeping. Train and supervise cold chain staff.	IV.D.7.
• Packaging wrong for the environment and drugs go bad.	• Specify packaging requirements in contract. • Carefully inspect drug shipments to assure supplier has used adequate packaging. • Maintain supplier file for merit rating and eliminate unsatisfactory suppliers.	III.B.2.j. IV.D.3. III.C.3.
• Drugs dispensed to patients without containers or in shoddy containers, causing deterioration of drugs.	• Prepackage drugs in course-of-therapy quantities in plastic packets suitable to the environment. • Use dispensing containers suitable to the environment, yet economical.	V.B.3.b. V.B.3.a.
4. <u>DRUGS ARE USED IMPROPERLY</u>.		
• Medical practitioners use unnecessary drugs, give drugs out for the wrong problems, give out several drugs for problems which one drug would treat.	• Strengthen pharmacology and therapeutics training for physicians and medical auxiliaries. • Develop standard norms for treatment. • Prepare standard reference manuals for health workers; provide periodic drug information circulars to inform about new drugs. • Limit prescribing privileges by level-of-use and level of training. • Oversee the actions of drug company representatives who encourage over-prescribing.	V.A.2.a. II.B.1. V.A.2.b. V.A.2.d. V.A.2.b.

PROBLEM Possible Causes	Corrective Actions	Reference in Manual
• Drugs mixed up on shelves, labels fall off bottles, wrong medicines given out.	• Prepackage drugs in course-of-therapy plastic packets with instructions included on packet.	V.B.3.b.
	• Develop dispenser training programs.	V.B.4.
	• Train and supervise health workers in dispensing practices.	V.B.4.
• Labels illegible or too abbreviated.	• Promote adequate labeling of drugs by dispensers and health workers.	V.B.1.
• Patient cannot read instructions.	• Prepare symbolic labels designed to help patients who are unable to read.	V.C.4.
• Patients don't follow medical advice.	• Increase awareness of factors influencing patient compliance.	V.C.1.
	• Make packaging and labeling more appealing.	V.B.3. V.C.4.
	• Use community education efforts to help increase patient understanding of medicines.	V.C.5.
• Patients want drugs for the wrong reasons and refuse drugs which might help.	• Promote individual patient education by prescriber and dispenser.	V.C.2. V.C.3.
	• Encourage community education about vaccines and medicines.	V.C.5.